Use of Cancer Patient Information for Surveillance Purposes

A Systematic Review of Legislation, Regulations, Policies and Guidelines

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Prepared for the Canadian Coalition on Cancer Surveillance by:

Barbara von Tigerstrom
Health Law Institute, University of Alberta

Mylène Deschênes
Centre de recherche du droit public, Université de Montréal

Bartha Maria Knoppers
Centre de recherche du droit public, Université de Montréal

Timothy A. Caulfield
Health Law Institute, University of Alberta

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For more information:
For more information on the Canadian Coalition on Cancer Surveillance or to obtain more copies of this report, please contact:

Anna Maria Boscaino or Brenda Branchard
CCOCS Secretariat Office
Tel: (613) 957-0355 or (613) 952-2775
email: anna_maria_boscaino@hc-sc.gc.ca
email: brenda_branchard@hc-sc.gc.ca
web site: http://www.hc-sc.gc.ca/hpb/lcdc/bc/ccocs/index.html

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1.01 Introduction

The aim of this document is to provide an overview of the legal context for cancer surveillance in Canada. It includes a review of relevant legislation and common law in all Canadian jurisdictions, in addition to selected codes, policies and procedures. Information from similar sources in other countries and from international agencies was reviewed to provide a basis for comparison with the Canadian context. This information is to be used to identify gaps or barriers in Canadian legislation and areas for further study or reform.

The project was undertaken by two research centres working in collaboration. The Health Law Institute at the University of Alberta was primarily responsible for collecting and analyzing the Canadian material, including legislation, common law and relevant standards and codes. Sources were identified by conducting electronic and library searches and through contacts at cancer registries across Canada. A literature review on cancer surveillance issues was also conducted.

The Centre de recherche en droit public at the Université de Montréal conducted the international research. Legislation and policies from other countries were collected and analyzed. The work of international agencies relevant to cancer research was also reviewed, including documents such as guidelines and recommendations relating to cancer registries. Further literature searches were conducted focusing on the international context. The research placed particular emphasis on privacy and confidentiality at the international level.

In order to collect the material for this project, inquiries were sent to all Canadian cancer registries and numerous registries and other agencies in other countries. Written inquiries were followed up with telephone conversations with registry personnel and government officials in many provinces and countries. The information gathered in this manner supplemented our research efforts using the internet, Quicklaw database and library resources. The content of this report is based on the most current information collected as of March 28, 2000. It should be noted that up-to-date material was much more readily available for some jurisdictions than others. Given the tremendous scope and dynamic nature of the subject matter, we cannot guarantee that the review is completely comprehensive; however, we feel confident that it discloses all relevant trends and issues related to this important area. To impose reasonable limits on the scope of the project, we have not dealt with the related areas of tissue banking or cancer screening; these raise many distinct issues that will need to be considered in detail elsewhere.

Section II of the report provides an overview of some relevant background material and current developments. Section III looks at the legal framework for cancer surveillance in Canada, including the common law, the *Charter of Rights and Freedoms* and the various types of legislation that may be relevant to cancer surveillance. Section IV provides a more detailed analysis of legislation, beginning with a summary of legislation on personal information and health information, followed by a review of the legislative framework in each Canadian jurisdiction. The last part of Section IV analyzes Canadian cancer legislation according to the performance criteria developed by the Canadian Coalition on Cancer Surveillance. Section V reviews some of the most important codes and guidelines relevant to cancer surveillance. Examination of the international material begins in Section VI with a description of international agencies relating to cancer and their activities and documents. Section VII describes the cancer registration systems in five selected countries. Section VIII discusses international standards with respect to privacy and data protection, and relevant legislation in four countries. Finally, Section IX outlines some issues and recommendations based on our research.

2.01 Context

This analysis has been undertaken in the midst of a period of significant evolution in terms of surveillance activities, development of health information systems, and legislation in the area of health information. A brief overview of these ongoing developments is included here to identify areas of importance to our analysis and to ensure that the analysis is as relevant and useful as possible in the current context.

2.02 Health surveillance context

2.02.1 HISTORY AND OVERVIEW OF HEALTH SURVEILLANCE

The concept and practice of health surveillance have been with us for centuries and continue to evolve. Early practice included monitoring and quarantine activities during the bubonic plague; more systematic action began in the 17th and 18th century.[1] Originally, the term "surveillance" was used to refer to personal surveillance of persons infected with or carrying serious communicable diseases and their contacts,[2] but more recently (in the 1950s-60s) it took on its current meaning.[3] Surveillance activities historically have focused on communicable diseases,[4] but now include chronic disease, injuries and other public health concerns. In Europe and the United States, mechanisms for mandatory reporting of communicable diseases were developed in the late 1800s,[5] while the establishment of cancer registries dates back to the 1940s.[6]

"Surveillance" has been variously defined:

1. Systematic measurement of health and environment parameters, recording, and transmission of data.
2. Comparison and interpretation of data in order to detect possible changes in the health and environmental status of populations."[7]
3. Tracking and forecasting any health event or health determinant through the ongoing collection of data, the integration, analysis and interpretation of that data into surveillance products and the dissemination of that resultant surveillance product to those who need to know. Surveillance products are produced for a predetermined public health purpose or policy objective. In order to be considered

The essential characteristics of surveillance are the ongoing or systematic collection, analysis and dissemination of data. Various types of surveillance have been distinguished, for example "active surveillance," in which data are obtained by a proactive search and contact with health care providers, in contrast to "passive surveillance," in which the recipient of the data initiates or establishes a system

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[1] Stephen B. Thacker, "Historical Development" in Steven M. Teutsch & R. Elliott Churchill, eds., *Principles and Practice of Public Health Surveillance* (New York & Oxford: Oxford University Press, 1994) 3 at 3-4.

[2] Thacker, *ibid.* at 5-6; W. J. Eylenbosch & N. D. Noah, "The surveillance of disease" in W. J. Eylenbosch & N. D. Noah, eds., *Surveillance in Health and Disease* (Oxford: Oxford University Press, 1988) 9 at 9.

[3] Thacker, *supra* note 1 at 5-6.

[4] Thacker, *ibid.* at 4; Eylenbosch & Noah, *supra* note 2 at 9.

[5] Nancy E. Stroup, Matthew M. Zack & Melinda Wharton, "Sources of Routinely Collected Data for Surveillance" in Teutsch & Churchill, *supra* note 1, 31 at 33.

[6] *Ibid.* at 55.

[7] World Health Organization, as quoted in Eylenbosch & Noah, *supra* note 2 at 9.

but then waits for health care providers to report, possibly pursuant to a legal or other duty to provide information.[8]

These types of systems may be used in combination. Furthermore, a combination of the various possible sources of information may be used. Common sources include the following:[9]

1. Notifiable disease and related reporting systems;
2. vital statistics;
3. Sentinel surveillance (using a selected sample to monitor key health indicators in the general population);
4. Registries;
5. Surveys; and
6. Administrative data-collection systems.

Registries differ from other sources in that they link data from multiple sources into consolidated information for each individual.[10] This linking allows each new case to be identified but not counted more than once. The use and importance of registries have increased in recent years.[11]

Specific sources used in Canada include "hospital inpatient separations, hospital outpatient data, provider payment data (mainly for physicians), vital statistics (birth, death, stillbirth), laboratories, local public health agencies, cancer registries, coroners, veterinary sources, and drug plans."[12] The number and diversity of sources used will likely increase as technology facilitates sharing of information and as greater attention is paid to a broader range of non-medical factors and determinants of health.

2.02.2 HEALTH SURVEILLANCE IN TRANSITION

The diversity of methodologies and sources in health surveillance provides an essential flexibility, but may also be an impediment to the extent that it limits the effective sharing and use of information. "At present, information networks in Canada's health sector function as independent 'islands of activity', lacking coordination and strong links across boundaries of geography and subject matter. The result is fragmentation, duplication of efforts, inaccessible health information and reduced value for the funds that are being expended."[13] *Ad hoc* development of systems in response to specific needs has left gaps[14] and created a system of isolated mechanisms.

Work is under way to identify and address weaknesses and opportunities for improvement in health surveillance. For example, the Auditor General of Canada completed an audit of national health surveillance, the results of which are presented in a 1999 report and have been responded to by Health

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[8] Eylenbosch & Noah, *supra* note 2 at 17.

[9] This list is based on Stroup, Zack & Wharton, *supra* note 5.

[10] *Ibid.* at 51.

[11] *Ibid.* at 51, 55.

[12] *Proposal*, *supra* note 8 at 9.

[13] *Ibid.* at 15-16.

[14] *Ibid.* at 16.

Canada.[15] Other recent documents include the report of the Advisory Committee on Women's Health Surveillance.[16]

Improvement of health surveillance functions is part of HPB Transition, the initiative to renew Health Canada's Health Protection Branch. HPB Transition includes legislative reform and surveillance transition, both of which are directly relevant to the current context for cancer surveillance. The legislative reforms being envisaged include development of umbrella legislation setting out federal roles and responsibilities in health protection. This legislation could include provisions regarding "the protection of privacy and confidentiality of personal data while also allowing for the collection, analysis, interpretation and distribution of surveillance data as a tool to efficiently manage health risks."[17] The Surveillance Transition's aim is to "strengthen and expand the Health Protection Branch (HPB) overall surveillance capacity to support an integrated health surveillance network for public health information from the local to the global level."[18]

The development of a National Health Surveillance Network is being proposed as part of the surveillance transition. This is not a centralized database, but rather a set of "tools and approaches" to allow "surveillance data collected by one Network partner to be shared in a timely manner by others, according to agreed-upon, and known, procedures and rules."[19] This should lead to enhanced capacity and quality. Development of the Network requires agreement on roles and responsibilities, on use of data, including principles to ensure security and privacy rights, and on governing or coordinating mechanisms.[20]

Cancer surveillance is one of the more developed areas of health surveillance in Canada.[21] The Canadian Coalition on Cancer Surveillance is leading the development of an enhanced Canadian cancer surveillance system.[22] This initiative, of which this report forms a part, is linked to the broader changes in Canadian health surveillance in at least two important ways: first, cooperation with the National Health Surveillance Network could enhance the cancer surveillance system,[23] and second, cancer surveillance can be used as "a unique opportunity to test and develop the issues common to

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[15] Auditor General of Canada, *1999 Report of the Auditor General of Canada* (Ottawa: Auditor General of Canada, 1999), chapter 14.

[16] Advisory Committee on Women's Health Surveillance, *Women's Health Surveillance: A Plan of Action for Health Canada* (1999).

[17] Health Canada, "Health Protection Legislative Renewal" at http://www.hc-sc.gc.ca/hpb/transitn/3pager_e.htm.

[18] Health Canada, "Surveillance Transition" at http://www.hc-sc.gc.ca/hpb/transitn/surveile.htm.

[19] *Proposal*, *supra* note 8 at vi.

[20] *Ibid.* at ix.

[21] *Ibid.* at 16, 51.

[22] Canadian Coalition on Cancer Surveillance, *Canadian Coalition on Cancer Surveillance (CCOCS): A Five-year Business Plan* (1997) at 4.

[23] *Proposal*, *supra* note 8 at 51.

all health surveillance systems."[24]

2.03 Health information context

At the same time as these developments are taking place in health surveillance, important initiatives in the area of health information more generally are also under way. All across Canada, health information systems are being developed to facilitate the sharing of information for provision of health services, research, administration and other purposes; and at a national level, efforts are being made to allow for integration and sharing of information.

Some of the important components and actors in this area are as follows:[25]

- Office of Health and the Information Highway: Health Canada directorate, responsible for development of the Canada Health Info*way*
- Advisory Council on Health Infostructure: 24-member council established by the federal Minister of Health in 1997 to provide strategic advice on the development of a national strategy for a Canadian health infostructure (The Advisory Council on Health Infostructure produced its final report in 1999.[26])
- Canada Health Info*way*: the proposed health infostructure, which includes the technological framework; the information, applications and software; governance, management and standards for use of information; and the people and organizations involved in the network[27]
- Canadian Health Network: provision of health information to consumers via the internet and other media; one of three initiatives of the national strategy for a Canadian Health Infostructure
- First Nations Health Information System: basic infrastructure and capacity for health information management in First Nations communities; one of three initiatives of the national strategy for a Canadian Health Infostructure
- National Health Surveillance Infostructure: a "network of networks" for collection, integration and analysis of surveillance data; one of three initiatives of the national strategy for a Canadian Health Infostructure
- Health Information Roadmap: a joint initiative of the Canadian Institute for Health Information (CIHI), Statistics Canada and Health Canada
- Canadian Institute for Health Information: national, non-profit organization charged with developing and maintaining a comprehensive and integrated health information system
- SPHINX: Spatial Public Health Information Exchange, a national system integrating aggregate health-related data
- Provincial health information networks: e.g. Alberta we*ll*net, Saskatchewan Health Information Network, B.C. HealthNet

2.04 Legal context

The present context is also characterized by active development in the area of health information legislation and information/privacy legislation more generally. People are increasingly concerned about personal privacy, and many see the development of information technologies as a threat to

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[24] *Ibid.* at 3.

[25] Information in this list is derived from: *Proposal*, *supra* note 8, Appendix 5; Canadian Institute for Health Information, *Health Information Roadmap: Responding to Needs* (1999), Appendix A; Office of Health and the Information Highway web site online at http://www.hc-sc.gc.ca/ohih-bsi/menu_e.html.

[26] Advisory Council on Health Infostructure, *Canada Health Infoway: Paths to Better Health, Final Report* (Ottawa: Health Canada, 1999).

[27] *Ibid.*, chapter 1.

privacy.[28] We are in the midst of a "new wave" of legislative reform regarding the protection of personal information.[29] Most Canadian jurisdictions have had some form of privacy legislation in place for some time, either as part of Freedom of Information and Protection of Privacy (FOIPP) legislation or as a separate statute (e.g. the federal *Privacy Act*). However, in response to international developments (e.g. the European Union Data Protection Directive[30]) and to increasing public awareness and concern, there have been recent developments in two main areas: the expansion of legislative protection of personal information to include the private sector, and the development of comprehensive legislation specific to health information. The federal Bill C-6 (formerly C-54) is an example of the first; new health information legislation in Manitoba, Saskatchewan and Alberta, and draft legislation in Ontario, are examples of the second.

The success of the Canada Health Infoway and similar projects under way at the national and provincial levels will depend on the development of a comprehensive and consistent legislative framework for the protection of personal health information. The Final Report of the Advisory Council on Health Infostructure noted that "a real danger exists that Canada could end up with many different approaches to privacy and the protection of personal health information." It recommended that harmonization of provincial and federal approaches be encouraged and that "all governments in Canada should ensure that they have legislation to address privacy protection specifically aimed at protecting personal health information through explicit and transparent mechanisms."[31] In addition, it recommended that privacy legislation applicable to health information bind the public and private sectors.[32]

The legislative renewal program within Health Protection Branch Transition is another relevant part of the current legal context. The review and proposed new legislation include delineation of roles and responsibilities, division of powers, risk management, scientific freedom and safeguards for confidentiality and privacy.[33]

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[28] See e.g. B. von Tigerstrom, "Protection of Health Information Privacy: The Challenges and Possibilities of Technology" (1998) 4 Appeal 44.

[29] "The New Wave of Privacy Protection in Canada" was the title of a recent conference held March 9-10, 2000 in Vancouver.

[30] European Union, *Directive 95/46/EC of the European Parliament and of the Council on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data* [1995] O.J. L. 281.

[31] Advisory Council on Health Infostructure, *supra* note 27 at 5-2, 5-3.

[32] *Ibid.* at 5-3.

[33] Health Canada, *Shared Responsibilities, Shared Vision: Renewing the Federal Health Protection Legislation* (Discussion Paper) (Ottawa: Health Canada, 1998) at 35-36; Health Canada, *National Consultations Summary Report: Renewal of the Federal Health Protection Legislation* (Ottawa: Health Canada, 1999).

3.01 Legal regulation of cancer surveillance in Canada

3.02 Common law

"Public health surveillance and the law are joined by so many interconnecting links that virtually every aspect of a surveillance program is associated with one or more legal issues."[34] Although the focus of this investigation is *legislation* relevant to cancer surveillance, it is important, in order to have a complete picture of the legal context, to also be aware of the legal rules supplied by the common law. The common law is made up of a body of judicial decisions, independent of any statute or regulation, and is based on the concept of precedent. In Canada, the common law applies in all provinces except Quebec, where the civil law system prevails. A description of relevant Quebec civil law is provided in section 3.03 below.

This section describes the areas of law generally applicable to surveillance activities, and provides an overview of the legal framework for surveillance outside of any specific statute. The common law rights and duties described may be modified by legislative action: a statutory provision might change one of these rules or protect an individual from liability that might otherwise exist. Therefore it is essential to look at the interaction between common law and legislation to obtain a complete picture of the legal situation.

3.02.1 PRIVACY[35]

There is no discrete, common law action for breach of privacy in Canada. Privacy is protected by a network of legislation, constitutional provisions and various aspects of the common law. Health care providers have an obligation to maintain the confidentiality of patient information as part of their duties of care[36] and fiduciary duties[37] (see sections III.A.3 and III.A.4). A breach of privacy may also be grounds for other types of tort actions such as nuisance, trespass, libel, slander, defamation, assault or battery.[38] If there is a contractual relationship between the provider and patient, a duty of confidence may be considered to be implied in that contract.[39]

Health professionals also have ethical duties of confidentiality contained in, for example, the

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[34] Gene W. Matthews & R. Elliott Churchill, "Public Health Surveillance and the Law" in Teutsch & Churchill, *supra* note 1, 190 at 190.

[35] For a review of Canadian law relating to health information and privacy, see e.g. M. Marshall & B. von Tigerstrom, "Confidentiality and Disclosure of Health Information" in J. Downie and T. Caulfield, eds., *Canadian Health Law and Policy* (Toronto: Butterworths, 1999) 143.

[36] *Furniss v. Fitchett*, [1958] N.Z.L.R. 396; *Peters-Brown v. Regina District Health Board*, [1996] 1 W.W.R. 337 (Sask. Q.B.), aff'd [1997] 1 W.W.R. 639 (C.A.).

[37] *McInerney v. MacDonald*, [1992] 2 S.C.R. 138; 93 D.L.R. (4th) 415 [hereinafter *McInerney*, cited to D.L.R.].

[38] G. H. L. Fridman, *The Law of Torts in Canada*, vol. 2 (Toronto: Carswell, 1990) at 192ff; L. N. Klar, *Tort Law*, 2d ed., (Toronto: Carswell, 1996) at 66-67.

[39] *Mammone v. Bakan*, [1989] B.C.J. No. 2438.

Hippocratic Oath and the codes of ethics of various professional associations.[40] Although these are not legal duties *per se* they have some indirect force in law because a health professional who breaches them may be subject to discipline by a professional body under the authority of provincial legislation. These ethical duties may also be referred to as standards of conduct for the profession and thus be relevant to, for example, an action in negligence. Notwithstanding such ethical duties, a health professional is permitted to disclose information where disclosure is required by law. Ethical duties and guidelines specifically relevant to cancer surveillance will be further discussed in section V.

3.02.2 PROPERTY

In the eyes of the law, property is not a "thing" but a bundle of rights "enforceable against others."[41] The bundle may include, for example, the rights of possession, transfer and control. Although it is not clear how many of these rights need to be present before it can be said that someone clearly *owns* a given item, the right of exclusion is often considered the "essential stick in the bundle"[42] — that is, an owner holds a monopoly over whatever rights are present in a given bundle of rights. In the context of health care information this may include the exclusive right to control what is done with a health care record but need not include, for instance, a right of transfer. Therefore, "ownership" can mean different things in different circumstances. "[P]roperty is not a simple, self-explanatory term. The legal interests it represents in a particular case take their form from their context."[43]

In the context of surveillance programs the area of property law can play a role in a number of ways. For example, there are some commentators who believe that patients have an actual property interest in the information stored in their health care record. This is probably an inaccurate interpretation of the right of access affirmed by the Supreme Court of Canada in the case of *McInerney v. MacDonald*,[44] but it may seem that the qualified right of access created by the case (and codified in

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[40] E.g. Canadian Medical Association, *Code of Ethics*, (1996) 155 CMAJ 1176; Canadian Nurses Association, *Code of Ethics for Registered Nurses* (Ottawa: Canadian Nurses Association, 1997). The Canadian Medical Association has also produced a *Health Information Privacy Code*, (1998) 159 CMAJ 997, which deals specifically with privacy and confidentiality.

[41] B. Ziff, *Principles of Property Law* (Toronto: Carswell, 1996) at 2-3.

[42] See *ibid.* at 6; and M. Litman and G. Robertson, "The Common Law Status of Genetic Material" in B. Knoppers, T. Caulfield, and D. Kinsella, eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery, 1996) 51 at 58-59: "[T]he essence of property is the exclusive right of control or monopoly over the objects or subject matter of property."

[43] A. Weinrib, "Information and Property" (1988) 38 U. Toronto L. J. 117 at 121.

[44] *Supra* note 38. While the case is the source of the oft cited principle that "the physician or institution owns the physical record but the patient owns the information", no where in the judgment does Justice La Forest say that the patient "owns" or has a property interest in his/her health care information. Rather, he based the patient's qualified right of access on fiduciary law.
The fiduciary duty to provide access to medical records is ultimately grounded in the nature of the patient's interest in his or her records. As discussed earlier, information about oneself revealed to a doctor acting in a professional capacity remains, in a fundamental sense, one's own.
However, Justice La Forest does say that "the Doctor is the owner of the actual record." *Ibid.* at 425. See also B. Dickens, "Medical Records - Patient's Right to Receive Copies - Physician's Fiduciary Duty of Disclosure: *McInerney v. MacDonald*" (1994) 73 Canadian Bar Review 234; and *R. v. Stewart* (1988) 50 D.L.R. (4th) 1 (S.C.C.) at 10; "the protection afforded confidential information in most civil cases arises more from an obligation of good faith or a fiduciary relationship than from a proprietary interest."

legislation in a number of provinces)[45] is so strong that one could argue that it is "property like." Indeed, Justice La Forest uses language throughout the judgment that would seem to support an ownership approach (e.g. "The information conveyed [to the doctor] is held in a fashion somewhat akin to a trust.").[46]

Although stored tissue samples are beyond the scope of this review, it is important to note that they may create unique property issues.[47] As genetic research becomes increasingly common, a more thorough analysis of these issues will be warranted.

3.02.3 TORT LAW

In general, tort law "provides a legal means whereby compensation, usually in the form of damages, may be paid for injuries suffered by a party as a result of the wrongful conduct of others."[48] Subject to legislative exceptions, the principles of tort law could include have implications for all aspects of a surveillance program, including collection, storage, use and disclosure. For example, there have been a number of Canadian cases in which defendants have been found negligent in the handling of confidential health information. In the case of *Peters -Brown v. Regina District Health Board*, a hospital was found negligent in the way that it posted confidential health information — in this case, a list of individuals whose care would require body fluid precautions to be taken.[49] Although there is still a dearth of specific jurisprudence in this area,[50] there have been numerous judicial statements that have confirmed the existence of tort action for "breach of confidentiality."[51] Therefore, there seems little doubt that the handlers of health information can be found liable for the inappropriate use or disclosure of confidential information.

Another highly relevant area of tort law relates to the doctrine of informed consent. A well-established area of Canadian health law,[52] the doctrine of informed consent obligates health care professionals to provide patients with all "material information" concerning a proposed treatment, including the

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[45] E. Picard and G. Robertson, *The Legal Liability of Doctors and Hospitals in Canada* (Toronto: Carswell, 1996) at 406.

[46] *McInerney, supra* note 38 at 424.

[47] See e.g. Litman & Robertson, *supra* note 43.

[48] *Hall v. Hebert* (1993), 15 C.C.L.T. (2d) 93 at 118 (S.C.C.) cited in Klar, *supra* note 39 at 1. See also J. Fleming, *The Law of Torts*, 8th ed. (The Law Book Company, 1992) at 1.

[49] *Peters -Brown v. Regina District Health Board* [1995] S.J. No. 60 (Sask. Q.B.).

[50] Indeed, there are only a handful of Canadian cases which the result of a "breach of confidentiality": see e.g. *Mammóne*, *supra* note 40.

[51] *Hay v. University of Alberta Hospital*, [1990] 5 W.W.R. 78 at 80: "[A] physician who divulges confidential information could face an action for breach of confidentiality..."

[52] See in particular *Reibl v. Hughes* (1980) 114 D.L.R. (3rd) 1 (S.C.C.), and generally Picard & Robertson, *supra* note 46, chapter 3.

potential risks involved in the treatment. Founded largely on the ethical principle of autonomy,[53] the goal of informed consent is to enable the patient to have the information necessary to make an informed choice. "Material information" has been defined by the courts in very broad terms and has been held to include both medical and non-medical consideration (e.g., the risks of side effects and the potential social ramifications of a treatment choice). In general, a health care provider must provide the patient with any information that a reasonable person in the patient's position would want to know. Failure to provide this information constitutes negligence.

In the research setting the doctrine of informed consent is even more onerous. As noted by one commentator, "it is the most exacting duty possible, requiring 'full and frank disclosure' of all risks, no matter how remote, as well as all other material information about the research."[54] Of course, the doctrine of informed consent also relates to the use of patient information or tissue samples for the purposes of research.[55] In this regard, patients should be informed, for example, of the nature of the research project, how their data will be kept and who will have access to the information.[56] It is important to note that there is still some debate as to how the principles of consent would apply when the information used has been made anonymous. There are also additional issues in the context of stored tissue samples.[57]

Finally, the mandatory nature of cancer surveillance creates some interesting informed consent issues. Although a health care provider would seem ethically obligated to disclose the existence of a surveillance program, a patient cannot opt out of participation, and this may alter the legal significance of the consent process.

3.02.4 FIDUCIARY DUTIES

Fiduciary law compels those characterized as fiduciaries (e.g., physicians) to do that which is in the best interest of the beneficiary (e.g., patients). Canada is a country that places fairly onerous fiduciary obligations on health care professionals. Indeed, in the Supreme Court of Canada decision of *McInerney v. MacDonald* it was found that "[c]ertain duties do arise from the special relationship of trust and confidence between doctor and patient" and, therefore, physicians must "act with utmost

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[53] *Mallete v. Shulman* (1990), 72 O.R. (2d) 417 (Ont C.A.): "Individual free choice and self-determination are themselves fundamental constituents of life"; and *Ciarlarliello v. Schacter,* [1993] 2 S.C.R. 119: "[The] concept of individual autonomy is fundamental to the common law and is the basis for the requirement that disclosure be made to a patient."

[54] Picard & Robertson, *supra* note 46 at 150. See also, K. C. Glass, "Research Involving Humans" in Downie & Caulfield, *supra* note 36, 375. See also *Halushka v. University of Saskatchewan* (1965), 53 D.L.R. (2d) 436 (Sask. C.A.); and *Weiss v. Solomon* (1989), 48 C.C.L.T. 280 (Que. S.C.).

[55] To cite but one example see P. Reilly, M. Boshar and H. Holtzman, "Ethical issues in genetic research: disclosure and informed consent" (1997) 15 Nature Genetics 16.

[56] See Glass, *supra* note 55 at 392.

[57] See E. W. Clayton, et al., "Informed consent for genetic research on stored tissue samples" (1995) 274 JAMA 1786; R. Pentz, et al., "Informed consent for Tissue Research" (1999) 17 JAMA 1625; W. Grizzle, "The Pathologist's Role in the Use of Human Tissues in Research - Legal, Ethical and Other Issues" (1996) 120 Arch. Pathol Lab Med 909; J. Merz, "IRB Review and Consent in Human Tissue Research" (1999) 283 Science 1647.

good faith and loyalty"[58] in their dealings with patients. Similarly, in the case of *Norberg v. Wynrib*, Justice McLachlin stated that the "the most fundamental characteristic of the doctor-patient relationship is its fiduciary nature."[59] It is worth noting that although there are no Canadian cases in point, it is possible that health care institutions, such as hospitals, cancer boards or regional health authorities, could be held to be in a fiduciary relationship with patients.[60]

In the context of the cancer surveillance programs two features of fiduciary law are particularly relevant. First, fiduciary obligations arguably re-enforce the health care provider's obligations to "hold information received from or about a patient in confidence."[61] Second, and perhaps more significant, fiduciary law heightens the disclosure obligations of health care providers. In particular, it compels the comprehensive disclosure of information about actual and potential conflicts of interest. As such, it may compel physicians, researchers and, perhaps, institutions to disclose to patients the existence of incentives that may cause the physician to consider factors other than what is in the patient's best interest.[62] For example, in the well know California decisions of *Moore v. Regents of the University of California*[63] it was held that the defendant physician had a fiduciary duty to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."[64]

A patient's right to access to information about his or her health is also said to flow from the fiduciary duties of health care providers to their patients.[65] Although, as already noted, the health care provider owns the record, the patient has the right of access to the information it contains. This right is also codified in freedom of information and health information legislation.

3.02.5 INTELLECTUAL PROPERTY

The law relating to intellectual property comprises both common law and federal statute law in Canada; however, it is included in this section as an area of law relevant to cancer surveillance. Although a comprehensive analysis of intellectual property issues is beyond the scope of this study, it is important to be aware of issues that arise in this context.

Under Canadian copyright law, a compilation of data may be subject to copyright if the compilation

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[58] *McInerney*, *supra* note 38 at 423.

[59] *Norberg v. Wynrib* (1992) 92 D.L.R. (4th) 449 (S.C.C.);. See also *Henderson v. Johnston* (1956) 5 D.L.R. (2d) 524 (Ont. High Ct.); and *Cox v. College of Optometrists of Ontario* (1988) 65 O.R. 461 (Ont. High Ct.).

[60] See, for example, *Herdrich v. Pegram*, 1998 LEXIS 20189 (7th Cir. August 18, 1998).

[61] *McInerney*, *supra* note 38.

[62] See, for example, J. Martin and L. Bjerknes, "The Legal and Ethical Implications of Gag Clauses in Physician Contracts" (1996) 22 Am. J. L. & Med. 433 at 457: "Pursuing a claim for breach of fiduciary duty, particularly in conjunction with a claim for violation of informed consent, is likely to succeed based on the 'long history of judicial regulation of economic conflicts of interest in fiduciary relationships.'"

[63] *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990).

[64] *Ibid.* at 485. See also Picard & Robertson, *supra* note 46 at 133.

[65] *McInerney*, *supra* note 38.

involves "selection and arrangement." Therefore, the result of merely collecting data or sorting them in an obvious way will not be protected by copyright, but if some original contribution in the selection and/or arrangement of data is involved, copyright may apply.[66] This would prevent anyone other than the copyright owner (the "author" of the compilation) from copying or distributing the compilation without the owner's permission.

The contents of databases may also be protected as trade secrets or confidential information.[67]

3.03 Civil law in the province of Quebec

The legal system in Quebec is distinct from that in the rest of Canada because it is based on the civil law system and contains some unique features. In addition to the federal *Charter*, which serves as the ultimate filter of the constitutionality of all provincial and federal legislation (see section C.), Quebec has its own Charter. This *Charter of Human Rights and Freedoms*, which is of a quasi-constitutional nature, contains a right to respect for private life (article 5) and, more important, the "right to non-disclosure of confidential information" — this applying even in a court of law, absent authorization by the patient or by statute (article 9).

These provisions are buttressed by the *Civil Code of Quebec*, which since 1994 has contained a whole chapter with explicit provisions on the right to privacy as a right of personality. Both the *Charter* and the *Civil Code* cover both government as well as private action.

3.04 Constitutional law

Canadian constitutional law is relevant to the legal regulation of cancer surveillance in two important respects. First, it governs the division of powers between the federal and provincial governments, establishing the framework for roles and responsibilities. Second, the *Canadian Charter of Rights and Freedoms*[68] (the *Charter*) sets out the fundamental rights and freedoms that must be respected by any legal framework.

3.04.1 Division of powers

The division of powers between the federal and provincial governments is established in sections 91 and 92 of the *Constitution Act, 1867*. The federal and provincial governments have their own areas of exclusive jurisdiction in which they have the power to legislate. If a government tries to legislate outside of its area of jurisdiction, the law will be invalid. In the event of a conflict between valid federal and provincial laws, the federal law will prevail and the provincial law will be inoperative to the extent of the inconsistency. Where the laws are not inconsistent, however, there is potential for overlapping or concurrent jurisdiction. The categories listed in sections 91 and 92 sometimes require interpretation, and so, over the years, the courts have developed methods of analysis for determining whether laws fall within the federal or provincial areas of jurisdiction.

Health or public health generally is not listed as a specific area of jurisdiction, and neither level of government has exclusive power in this area. Both the federal and provincial governments can legislate with respect to certain aspects of health, according to the areas that are within their

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[66] D. Vaver, *Intellectual Property Law* (Concord, Ontario: Irwin Law, 1997) at 38; R. Howell, *Database Protection and Canadian Laws* (Industry Canada, 1998) at 61.

[67] Howell, *ibid.* at 64.

[68] Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11.

jurisdiction.

The federal government may rely on its power over criminal law (section 91(27)) for some health-related measures, for example to prohibit conduct that is harmful to health. Of special relevance to surveillance is section 91(6), which gives power over the census and statistics to the federal government. Quarantine and "marine hospitals" are also within federal jurisdiction (section 91(11)). The federal government has authority over "Indians, and lands reserved for the Indians," which is why, for example, health care for First Nations peoples is provided for by the federal government rather than as part of provincial health plans.

The federal government also has a residual power to make laws for the "peace, order and good government" of Canada. This could be used when a matter is not included in the list of powers, when there is some emergency or when the matter is of concern to all of Canada and cannot be effectively addressed by the provinces. The mere fact that consistent laws throughout the country would be desirable is not sufficient to justify the use of this power, however.[69]

The provinces have power over the establishment, maintenance and management of hospitals "other than marine hospitals" (section 92(7)). More generally, provincial activities in the area of health and health care can be justified under section 92(13) and 92(16), which grant the provinces power over "property and civil rights in the province" and "matters of a merely local or private nature in the province."

Provincial governments also have power, in section 92(8), over "municipal institutions in the province." Municipal governments (city and other local governments) do not have independent authority under the Constitution but exercise power that is delegated by the provinces.

Therefore, there are only two explicit levels of power in the Canadian Constitution: federal and provincial. However, we are also beginning to see the emergence of a third order of government as power is devolved to First Nations communities in recognition of their aboriginal and treaty rights.

As this brief summary should make clear, the division of powers in Canada is quite complex. In the area of health and health surveillance, both the federal and provincial governments have some authority, and so cooperative efforts will often be required.

3.04.2 *Canadian Charter of Rights and Freedoms*

The *Canadian Charter of Rights and Freedoms* applies

(a) to the Parliament and government of Canada in respect of all matters within the authority of Parliament including all matters relating to the Yukon Territory and Northwest Territories; and

(b) to the legislature and government of each province in respect of all matters within the authority of the legislature of each province.[70]

All government action is thus subject to the *Charter*, including all federal and provincial legislation, but also other types of official action such as the activities of government employees and officers in their official capacity, administrative decisions, etc. The *Charter* is part of the Constitution and

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[69] P. Hogg, *Constitutional Law of Canada*, 4th ed. (Toronto: Carswell, 1997) at 454.

[70] *Charter*, *supra* note 69, s. 32

therefore part of the supreme law of Canada. This means that any law that is inconsistent with the *Charter* "is, to the extent of the inconsistency, of no force and effect."[71]

A law or other government action that infringes on a *Charter* right may not be contrary to the *Charter* if the infringement can be "saved" under section 1 of the *Charter*. Section 1 states that the rights and freedoms set out in the *Charter* are guaranteed "subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society." Therefore, if the government can show that its action is such in a reasonable limit, there is no breach of the *Charter*. The test for this requires the government to show that (a) there is a "pressing and substantial" objective, (b) there is a rational connection between the objective and the measure, © the measure does not infringe on rights any more than necessary, and (d) there is proportionality between the infringement and the objective it is designed to achieve.

(A) PRIVACY

There is no specific section in the *Charter* that protects a right to privacy. Such a provision does exist in the constitutions of some countries and in various international human rights instruments.[72] In Canada, however (as in the United States), the courts have recognized that privacy is indirectly protected by certain provisions in the Constitution.

The key sections are section 7, which guarantees the right to "life, liberty and security of the person, and the right not to be deprived thereof except in accordance with the principles of fundamental justice," and section 8, which guarantees the right to be "secure against unreasonable search and seizure." The Supreme Court of Canada has stated in a number of cases that these sections include a right to privacy. Protection of privacy is seen as essential to human dignity[73] and liberty.[74] Because of the potentially traumatic effects of an unauthorized disclosure of personal information, an invasion of privacy may also violate an individual's security of the person.[75] The Court has stated that section 8 "should seek to protect a geographical core of personal information which individuals in a free and democratic society would want to maintain and control from dissemination to the state. This would include information which tends to reveal intimate details of the lifestyle and personal choices of the individual."[76]

The Court's decision also suggests, in particular, that protection should be provided to health information. Health information is most often disclosed in the context of a confidential relationship with a health care provider, and is thus confidential information. In a recent case involving counselling records, the Supreme Court of Canada confirmed that section 8 provides protection for such

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[71] *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11., s. 52

[72] E.g. *International Covenant on Civil and Political Rights*, 16 December 1966, Can. T.S. 1976 No. 47, 999 U.N.T.S. 171, article 17.

[73] *R. v. O'Connor*, [1995] 4 S.C.R. 411 at 487, per L'Heureux-Dubé J.; *R. v. Dyment*, [1988] 2 S.C.R. 417 at 432, per La Forest J.

[74] *R. v. O'Connor*, *ibid.* at 484, per L'Heureux-Dubé J.

[75] *R. v. Mills*, [1999] S.C.J. No. 68 (QL) at para. 85. See also *Canadian AIDS Society v. Ontario* (1995), 25 O.R. (3d) 388 (Ont. Gen. Div.) at 396.

[76] *R. v. Plant*, [1993] 3 S.C.R. 281 at 293.

confidential information, and indirectly for the therapeutic relationship.[77] In other cases, in which body sample taken without consent or for medical purposes only were used in criminal proceedings, the Court has held that the individual had a reasonable expectation of privacy in part because of the relationship of confidence with the health care provider.[78]

Violations of privacy that occur as a result of legislation or some other government action could therefore potentially infringe individuals' *Charter* rights. If there is a violation, the government would have to show that it is justified according to the test set out above. In the case of section 7 rights, there is no violation if the rights are infringed "in accordance with the principles of fundamental justice."

(B) EQUALITY RIGHTS

Section 15(1) of the *Charter* provides that "Every individual is equal before and under the law and has the right to the equal protection and equal benefit of the law without discrimination and, in particular, without discrimination based on race, national or ethnic origin, colour, religion, sex, age or mental or physical disability."

Section 15(2) provides for an exception where a law, program or activity is directed at "the amelioration of conditions of disadvantaged individuals or groups," allowing for affirmative action initiatives to be undertaken without violations s.15.

The test for when a law violates s.15 is the following:

a) Does the impugned law (a) draw a formal distinction between the claimant and others on the basis of one or more personal characteristics, or (b) fail to take into account the claimant's already disadvantaged position within Canadian society resulting in substantively differential treatment between the claimant and others on the basis of one or more personal characteristics?

b) Is the claimant subject to differential treatment based on one or more of the enumerated and analogous grounds?

and

c) Does the differential treatment discriminate, by imposing a burden upon or withholding a benefit from the claimant in a manner which reflects the stereotypical application of presumed group or personal characteristics, or which otherwise has the effect of perpetuating or promoting the view that the individual is less capable or worthy of recognition or value as a human being or as a member of Canadian society, equally deserving of concern, respect, and consideration?

All three elements of this test have to be satisfied for a law to be considered discriminatory.

In the context of surveillance, a law requiring mandatory reporting of information for one group (identified by disease or some other factor), for example, might be challenged as imposing a discriminatory burden on members of the group. Such a claim would have to establish that the distinction was based on an enumerated or analogous ground (i.e. one of those listed in s. 15 or a similar one). A distinction based on a certain disease or condition could be argued to be on the basis

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[77] *R. v. Mills*, *supra* note 76 at para. 79-82.

[78] *R. v. Dyment*, *supra* note 74; *R. v. Dersch*, [1993] 3 S.C.R. 768.

of physical disability. There is no clear case law in Canada on what the definition and scope of physical disability should be.[79] It is possible that a court could conclude that this is a disability or a ground analogous to disability. The claimant would also have to establish that the distinction was actually discriminatory in the sense described by the third part of the test. This might be possible if, for example, there were some preexisting disadvantage or stigma to the condition – unlikely for cancer in general, but possible in other cases depending on the category as defined in the law.

If a law was found to be discriminatory, the government could of course seek to establish that it was justified under section 1 as already discussed.

Section 28 of the *Charter* also states that the rights in the *Charter* are guaranteed equally to male and female persons. This might be relevant if one gender were subject to a greater infringement of privacy than another under some law or government policy.

(C) FREEDOM OF EXPRESSION AND ACADEMIC FREEDOM

Like privacy, academic freedom is not specifically protected in our *Charter*. However, it can best be described as a cluster of rights, some of which are included in the *Charter*'s scope. For example, the following freedoms are protected by section 2:

- freedom of conscience and religion;
- freedom of thought, belief, opinion and expression, including freedom of the press and other media of communication;
- freedom of peaceful assembly; and
- freedom of association.

These could be used to argue against any restriction on publication or dissemination of results, for example when surveillance data are used for research. Freedom of expression may equally be relevant outside the academic context, since it applies to all individuals in Canadian society. Freedom of expression has also been understood to include the right to receive information.[80] It could therefore be argued, for example, that individuals have a right to surveillance products such as information about rates of disease, risk factors and other health-related information. (Access to information legislation is obviously relevant in this context as well.)

The freedom to impart and receive information is not, of course, absolute, and in the context of health surveillance it is most likely to be limited by the protection of privacy. There may also be other valid reasons to restrict dissemination of information, such as concerns about data quality, appropriate presentation of data to the public, etc. However, given the constitutional protection of freedom of expression, it is important that any such restrictions are defensible as "reasonable limits" in the event of a challenge.

3.05 Legislation relevant to cancer surveillance

This section will provide an overview of the various types of legislation relevant to cancer surveillance in Canada. A more detailed review of the legislative scheme governing surveillance in each jurisdiction

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[79] There is a recent case in which it was argued that infertility is a physical disability: *Cameron v. Nova Scotia (Attorney General)* (1999), 177 D.L.R. (4th) 611; [1999] N.S.J. No. 297 (QL). The Nova Scotia Court of Appeal concluded that infertility is a disability for the purposes of the *Charter*, but leave to appeal this decision to the Supreme Court of Canada is being sought.

[80] *Edmonton Journal v. Alberta (Attorney General)*, [1989] 2 S.C.R. 1326: freedom of expression "protects listeners as well as speakers" (at 1339, per Cory J.).

is provided in the next section (section 4).

In any one jurisdiction, there may be a number of different statutes and regulations relevant to health surveillance and cancer surveillance in particular:

Cancer-specific Legislation	▸ with or without specific provisions regarding a registry
Public Health Legislation	▸ reporting requirements may deal only with communicable diseases or may have a broader scope, including cancer
Freedom of Information and Protection of Privacy (FOIPP) Legislation	▸ dealing with access to and protection of government-held information ▸ the access to information and privacy aspects may be dealt with in a single statute, or as separate pieces of legislation
Health Information Legislation	▸ specific, comprehensive legislation similar to FOIPP, dealing with health information
Other privacy legislation	▸ e.g. legislation that establishes a cause of action so that individuals can sue for breach of privacy, legislation regarding personal information in the private sector (federal Bill C-6)
Health Administration Legislation	▸ e.g. establishing the powers and functions of the health ministry (e.g. federal *Department of Health Act*) or administration of provincial health insurance schemes ▸ these may also contain provisions as to confidentiality and disclosure of information
Vital Statistics or Other Statistics Legislation	▸ vital statistics legislation requires registration of death and completion of medical certificates specifying cause of death ▸ statistics legislation provides statutory authority for collection, analysis and publication of statistics ▸ both will also contain rules about disclosure of information

The provinces also have legislation on occupational health and/or workers' compensation, which may include reference to cancer and/or contain reporting obligations for occupational diseases including some cancers.[81] However, because these are generally distinct schemes we have not included them in our analysis.

Most jurisdictions have some kind of legislation in each of these categories except for cancer-specific legislation, health information legislation and other privacy legislation; which exist only in some jurisdictions.

[81] E.g. *Occupational Health and Safety Act*, R.S.A. 1980, c. O-2 and *Chemical Hazards Regulation*, AR 393/88 in Alberta.

Generally speaking, these pieces of legislation fulfill one or more of several functions:

- setting out the powers and duties of an organization, e.g. Department or Minister of Health or cancer agency
- providing for the establishment of a registry
- allowing or requiring collection/recording/registration of certain information
- allowing or requiring disclosure of certain information, including mandatory reporting requirements, access for research and other purposes
- requiring confidentiality and prohibition of non-permitted disclosures
- protecting from liability for permitted disclosures
- allowing agreements to be made with specified bodies, e.g. other governments

4.01 Analysis of cancer surveillance legislative structure

4.02 Canadian legislation on personal and health information protection

Almost all Canadian jurisdictions have some form of legislation protecting personal information held by government bodies.[82] Three jurisdictions (Manitoba, Saskatchewan and Alberta) have also passed legislation specific to health information. So far Quebec is the only province with legislation protecting personal information in the private sector. The federal government has introduced a bill (Bill C-6) that covers the private sector.

This section will summarize the provisions of FOIPP legislation and health information legislation that may be relevant to cancer surveillance. It should be noted that although the cancer agency or registry in a province is normally covered by one or both of these statutes where they exist, the legislation in each jurisdiction must be examined to determine exactly to which bodies it applies. In addition to the cancer agency, other relevant bodies may be covered, for example health ministries, hospitals and other government agencies.

For the most part, the provincial and federal statutes are very similar in structure and content.[83] Access to information provisions[84] outline a right of access to information (generally, and/or one's own personal information), subject to exceptions, and describe how the right may be exercised. With respect to information about oneself there is a right to request corrections to this information. Another part of the legislation typically deals with collection, use and disclosure of information. These provisions will be described in greater detail later. Finally, there are supervision and enforcement mechanisms, giving authority to an information and privacy commissioner, ombudsman or similar official to receive and investigate complaints regarding alleged violations, to give permission for certain actions, and other functions.

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[82] See the table in Appendix A under FOIPP and Health Information. Prince Edward Island has no legislation in this area and Newfoundland has only a *Freedom of Information Act*, not personal information protection legislation. New Brunswick only recently enacted its *Protection of Personal Information Act* and it is not yet in force. Some jurisdictions have separate legislation for local or municipal government bodies (e.g. Saskatchewan, Ontario).

[83] New Brunswick's new legislation has quite a different structure, essentially adopting the CSA Model Code.

[84] These may be contained in the same statute as personal information protection provisions or, for example in the case of federal legislation, in a separate act.

4.02.1 SCOPE OF APPLICATION

There are two important definitional provisions that determine the scope of application of these statutes: the definition of the persons or bodies who are subject to the law, and the definition of the information that is covered by the law.

FOIPP legislation generally applies to "public" or "government" bodies. However, exactly what this includes and whether health care institutions are covered may vary from jurisdiction to jurisdiction. The provincial cancer agency may be explicitly included (e.g. under Alberta's *FOIPPA* or the regulations under Saskatchewan's *Local Authorities FOIPPA*) or implicitly included (e.g. in British Columbia).

Health information legislation applies to "custodians" or "trustees," which will include government departments and officials, but also health care facilities, health service providers and health professionals. In all three health information statutes, the provincial cancer board/foundation is explicitly included. (In Ontario's draft legislation there is no explicit mention of Cancer Care Ontario but it seems to be included as a health authority.)

Definitions of personal information are fairly consistent:

- name, address and telephone number
- race, national or ethnic origin, colour, religious or political beliefs or associations
- age, sex, marital and family status
- fingerprints and blood type; some include "inheritable characteristics"
- information about the individual's health and health care history, including disability
- educational, financial, criminal or employment history
- identifying number, symbol or other particular assigned to the individual

Health information legislation contains definitions of personal health information. These are structured differently in the various pieces of legislation, but generally include the following:

- information about the physical or mental health of the individual
- information about health services provided to the individual
- payment information
- registration information (including health number)
- information collected in the course of providing health services
- information about the donation of body parts or substances, including information derived from testing or examination of these (Alberta and Saskatchewan)

The Manitoba legislation specifically includes genetic information.

The most important limiting element in the definitions of personal information and personal health information is that they include only information about identifiable individuals. In a few cases this limit is not contained in the definition itself but rather in a later provision or provisions (e.g. in Saskatchewan and Alberta health information statutes); but in all cases the rules in these statutes apply only to information about identifiable individuals and not to anonymous information.

4.02.2 COLLECTION OF PERSONAL INFORMATION

Under FOIPP legislation, personal information may be collected only when the collection is authorized by law and required for the programs or activities of the collecting body. Under the New Brunswick Act, the purposes for which information is collected must be identified and documented, and they must relate directly to an existing or proposed activity of the collecting body. Health information legislation limits collection of personal health information to what is necessary for the purpose for which it is being collected; some (e.g. Alberta and the Ontario draft) require only non-

identifying or aggregate information to be collected unless identifying information is necessary for the purpose. The health information statutes also contain specific provisions limiting the collection of health numbers.

The general rule is that personal information must be collected directly from the individual who is the subject of the information. This rule is subject to exceptions, for example if the individual has consented to another method of collection or if the information could be disclosed to the collecting body in accordance with the statute's disclosure provisions. Some statutes contain more extensive exceptions, for example, when collection is in the individual's interest and direct collection is impracticable, or direct collection would likely result in inaccurate information. Health information legislation adds exceptions when direct collection could prejudice the health or safety of an individual. The Alberta *Health Information Act* allows information to be collected indirectly when direct collection is "not reasonably practicable."

Individuals must be informed of the purposes for which information is being collected and, in some cases, of other information, such as the legal authority for collection and whom to contact with questions regarding collection.

4.02.3 USE OF INFORMATION

Under FOIPP legislation, personal information may be used for the purposes for which it was collected or consistent purposes, for other purposes with the individual's consent, or for any purpose for which the information may be disclosed to the user under the legislation.

Different approaches are taken in the health information statutes. The Manitoba and Saskatchewan statutes and the Ontario draft contain provisions similar to the FOIPP statutes, but also add some other permitted uses. The Alberta statute simply lists the permitted purposes. These statutes allow personal health information to be used for several purposes:

- providing health services (Alberta)
- determining or verifying eligibility for health services (Alberta)
- purposes related to professional discipline (Alberta)
- providing education to health services providers (Alberta)
- purposes authorized by other laws (Alberta, Manitoba)
- internal management purposes (Alberta) or administration (Ontario)
- obtaining payment for health services (Saskatchewan)
- as prescribed by regulation (Saskatchewan)
- de-identifying the information (Saskatchewan)
- where necessary, preventing or lessening a serious and immediate threat to an individual's mental or physical health or safety, or public health or safety (Manitoba)
- participating in a proceeding in which the custodian is likely to be a party or witness (Ontario)
- research, with the approval of an ethics committee (Alberta,[85] Ontario)

In Alberta, certain health information custodians (including the Alberta Cancer Board, regional health

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[85] The exact wording of the Alberta provision (s. 27(1)(d)) states that personal health information may be used for conducting research:

> (I) if the custodian has submitted a proposal to an ethics committee in accordance with section 49,
> (ii) if the ethics committee is satisfied as to the matters referred to in section 50(1)(b), and
> (ii.1) if the custodian has complied with or undertaken to comply with the conditions, if any, suggested by the ethics committee, and
> (iii) where the ethics committee recommends that consents should be obtained from the individuals who are the subjects of the health information to be used in the research, if those consents have been obtained

authorities and the Department of Health and Wellness) may also use personal health information for planning and resource allocation, health system management, public health surveillance and health policy development. Manitoba's Act allows public bodies and health care facilities to use information to deliver, monitor or evaluate programs for provision or payment of health care, or for research and planning relating to provision or payment of health care.

4.02.4 DISCLOSURE OF INFORMATION

Under FOIPP legislation, personal information typically may be disclosed with consent, for the purposes for which the information was collected or consistent purposes, or for certain other specified purposes. The statutes allow personal information to be disclosed for research purposes provided certain conditions are met. The research purpose must require the disclosure of individually identifying information. Under some statutes (e.g. Manitoba, Alberta) there must be consideration of the potential harm or benefit of the research. The person or body to whom the information is to be disclosed must agree to certain restrictions and obligations with respect to use, security and non-disclosure. In some cases the provisions of the agreement or undertaking are set out in more detail in regulations.

The health information statutes allow personal health information to be disclosed only with consent or as specified in the list of exceptions. These exceptions, which are quite numerous, include disclosure for reasons such as provision of health services, for court proceedings, to avert some danger to another person or for contacting friends and relatives. Each of the health information statutes also contains separate provisions regarding disclosure of personal health information for research. There is some variation among these provisions.

In Alberta, approval by an ethics committee is required before the researcher can even apply for the information. If access is to be granted, conditions recommended by the ethics committee and/or the custodian will be imposed and an agreement will be entered into in which the researcher agrees to comply with certain conditions. The information may then be disclosed. The researcher may be required to pay for the preparation and copying of information and the obtaining of any necessary consents, but the cost may not exceed the actual cost of providing the service. Consent from the individuals is required before the researcher may contact any of the subjects for additional information.

The Saskatchewan statute allows trustees to use or disclose personal health information for research *with express consent of the subject individuals* where the research project is not contrary to the public interest, where it has been approved by a research ethics committee and where the researcher enters into an agreement dealing with use, disclosure, security, destruction, etc. If all of these conditions are met *and* it is not reasonably practicable for consent to be obtained, then the trustee may use or disclose personal health information if the research purposes cannot be accomplished using de-identified information or other information, personal health information not required for the research is removed and, in the opinion of the ethics committee, the potential benefits of the research clearly outweigh the potential risk to privacy.

In Manitoba, personal health information may be disclosed for a health research project if it is approved by the health information privacy committee (if the information is held by the government) or by an institutional research review committee. Approval may be given if the research is of sufficient importance to outweigh the infringement of privacy, if the research purpose cannot reasonably be accomplished without identifying information, if it is unreasonable or impractical to obtain consent, and the project contains reasonable safeguards to protect confidentiality and security as well as procedures for destruction of the information or rendering it anonymous at the earliest opportunity. An agreement regarding use, non-disclosure and safeguards is required. If the research requires

individuals to be contacted, consent must first be obtained unless the only information disclosed is names and addresses.

Finally, the Ontario draft health information statute allows custodians to disclose personal health information for research if the objective cannot reasonably be accomplished using other information, the research is not contrary to the public interest, research ethics review approval has been obtained if it is required by law or the funding agency, and the researcher enters into an agreement with specified terms.

4.02.5 OTHER RELEVANT PROVISIONS

FOIPP legislation and/or regulations require public bodies to take reasonable measures to ensure the security of personal information in their custody or control. Specific standards may be set by regulation. There may also be provisions regarding the retention and disposal or destruction of records. Health information statutes contain similar requirements regarding security and disposal.

Some statutes contain specific provisions regarding electronic records and matching or linking of data. In Manitoba, the FOIPP Act requires any proposal for data linking or matching, or request for bulk disclosure of personal information to be approved by the head of a public body with the advice of a review committee. The Alberta health information statute allows custodians to perform data matching with personal health information in its own custody or control, or with information from another custodian or other person after a privacy impact assessment has been prepared and submitted to the Commissioner for comment. If data matching is for the purposes of research, the provisions for disclosure of information for research must also be complied. The Ontario draft legislation also contains quite detailed provisions on record linkage, including requirements for an assessment to be submitted to the Commissioner and for individual access to records created by data linkage.

The Saskatchewan health information statute contains provisions on electronic records allowing individuals to require trustees not to store their records (or parts of them) on the Saskatchewan Health Information Network (SHIN), or to prevent access by other trustees to certain information. Trustees must inform individuals from whom data are collected if they have entered into agreements to store information on the SHIN. An earlier version of the Alberta legislation had a similar provision;[86] the new statute requires consent for disclosure of information by electronic means. This consent cannot be limited (it allows disclosure by any custodian for any purpose) but can be revoked.

The Manitoba health information statute prohibits the sale of personal health information (with limited exceptions regarding changes in ownership of a pharmacy or professional practice).

4.03 Legislative structure for cancer surveillance in the Canadian jurisdictions

There is considerable variation among Canadian jurisdictions as to the legislative structure for cancer surveillance. Some provinces have very little specific legislation in place, whereas detailed provisions exist in others.

Attached as Appendix A is a table of relevant legislation from each Canadian jurisdiction. The following is a summary of the legislative structure in each jurisdiction.

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[86] Bill 30, *Health Information Protection Act*, 1st Sess., 24th Leg., Alberta, 1997, s. 16.

4.03.1 YUKON

There is no specific legislation for cancer or cancer registry in the Yukon. The reporting and surveillance provisions in public health legislation deal only with communicable diseases. The administrator of the hospital insurance plan and director of the health care insurance plan have authority under the *Hospital Insurance Services Act* and the *Health Care Insurance Plan Act* respectively to "conduct surveys and research programs and obtain statistics for such purposes." The Minister's responsibilities under the *Health Act* include identifying health indicators, studying causes of health dysfunction and possible measures, conducting or sponsoring research into health issues, collecting information about health and health services, and informing and educating the people of the Yukon about health issues.

There is no specific legislation for cancer or cancer surveillance in the following provinces: Yukon, Quebec New Brunswick and PEI.

The *Vital Statistics Act* requires registration of death and a medical certificate stating the cause of death according to the international classification. The registrar is permitted to compile, publish and distribute statistical information about registered events, including deaths. There is a general confidentiality requirement precluding access by any unauthorized person, but statistical information is excepted. The Commissioner may make regulations designating persons who may have access to information. The provisions of this Act apply despite the *Access to Information and Protection of Privacy Act*.

There is no health information legislation or privacy act in place in the Yukon. The primary statute for personal information is the *Access to Information and Protection of Privacy Act*. The Act applies to personal information, which is only information about an identifiable individual and includes health information. It applies to public bodies, including departments, boards, commissions, foundations, etc. The provisions of this Act prevail over other legislation unless expressly provided otherwise (e.g. *Vital Statistics Act*). The Act contains the usual provisions giving a right of access to information (and exceptions) and defining limits on collection, use and disclosure, including a specific provision for disclosure for research purposes.

The *Health Act* contains a section setting out the rights of "clients" including the right to "have their relationship with a health services ... worker and the information about their treatment or service to be kept confidential." This right does not, however, preclude disclosure necessary for appropriate treatment, permitted or compelled by law, with consent or for the protection of another person.

4.03.2 BRITISH COLUMBIA

Cancer surveillance is not provided for in a separate statute but is specifically dealt with in the *Health Act* and an associated regulation. Section 9 of the *Health Act* allows the B.C. Cancer Agency to request information or records prescribed by regulation, where this will facilitate medical research and benefit the public. When a request is made it must be complied with in the manner and at the times requested, subject to another law. When information has been received under this section, it must not be disclosed except for medical research; in court proceedings; in accordance with an agreement with a government, government agency or other organization for medical research; or for compiling statistical information for medical research. There is protection from liability for anything done or omitted in good faith under this section. A regulation sets out the specific categories of information that may be requested.

The *Health Act* also provides (in s. 10) for a health registry, which records and classifies congenital anomalies, genetic conditions or chronic handicapping conditions. The registry may request information on these conditions and the request must be complied with in the manner and at the times requested if the information is in a person's possession or control. Information may be disclosed only in the same situations that apply with respect to the cancer agency.

The *Health Act* is also the public health legislation, but the notification requirements deal with communicable diseases only.

British Columbia has both a *Vital Statistics Act* and a *Statistics Act*. The *Vital Statistics Act* requires registration of death and a medical certificate stating the cause of death according to the international classification. It allows compilation, publication and dissemination of statistical information. Confidentiality provisions prohibit disclosure or access except for statistical data that does not identify individuals. All records etc. are the property of the government. The *Statistics Act* provides authority for the collection, compilation, analysis, distribution, etc. of statistical information and for assistance to ministries with these activities. Statistical activities may be coordinated with statistical agencies of other governments, and there are provisions for disclosure to and agreements with Statistics Canada and other bodies. There is a confidentiality provision which is paramount over the *Freedom of Information and Protection of Privacy Act*, and the director and employees are required to swear an oath of secrecy.

The *Privacy Act* provides for a tort action without proof of damages where privacy is violated wilfully and without a claim of right. Confidentiality of "matters that identify an individual beneficiary or practitioner" is required under the *Medicare Protection Act*.

British Columbia has a *Freedom of Information and Protection of Privacy Act*, which applies to public bodies such as the cancer agency and other health care bodies. It contains provisions on access, collection, use and disclosure, including disclosure for research. The Act's provisions are paramount over other legislation unless expressly provided otherwise.

The British Columbia Cancer Agency provided a copy of its Policy No. IV-D-30, "Access to Cancer Registry Data." The Policy applies to "all requests processed for the intra-provincial, national, or international Registries." It states that requests for access will be managed in accordance with the *Freedom of Information and Protection of Privacy Act*. Before receiving approval for access to identifying data, researchers will be required to sign a research agreement (requiring data to be protected in accordance with s. 35 of the *Freedom of Information and Protection of Privacy Act*) and a confidentiality agreement.

The "Cancer Registry Identifying Data Request" serves as an application for access, but also as a confidentiality agreement if the request is approved. It refers to the *Freedom of Information and Protection of Privacy Act* and contains a "Security Provisions and Confidentiality Agreement," "Pledge of Confidentiality," "Review Authorization" and "BCCA Authorization."

4.03.3 ALBERTA

Alberta has perhaps the most fully developed legislative scheme relating to cancer surveillance. Part 1.1 of the *Cancer Programs Act* deals with the cancer registry. It provides for the establishment of the registry, which may contain information from specified sources.

Alberta has perhaps the most fully developed legislative scheme relating to cancer surveillance.

The information in the registry may be used for specified purposes and is private and confidential. There is a mandatory reporting requirement for reportable cancers (as defined by the regulations): physicians and laboratories are required to provide information prescribed by the regulations. The board may also request any additional information considered necessary. Physicians and laboratory personnel are protected from liability for providing information under this section. The Minister or board may enter into an agreement with a government or any person for disclosure of information in the registry; this agreement must require the information disclosed to remain confidential. The Act also sets out when and to whom information in the registry may be disclosed. Other disclosures are prohibited, and unauthorized disclosure or access is an offence.

The *Cancer Programs Regulation* defines reportable cancers as the "list of all diseases classified as malignant, *in situ* or metastatic in the International Classification of Diseases for Oncology, as amended from time to time, published by the World Health Organization." The regulations also establish the registry and list the information to be reported by physicians and laboratories.

The *Alberta Health Care Insurance Act* contains a general provision on confidentiality, one subsection of which allows disclosure of information to, *inter alia*, the Alberta Cancer Board where the information is requested in writing and is necessary and relevant to a matter dealt with by the Board. The *Alberta Health Care Insurance Regulation* requires that when a practitioner claims benefits with respect to diagnosis or treatment of cancer, information regarding the claim must be reported to the Alberta Cancer Board, from time to time, on the prescribed forms.

Reporting obligations are also contained in the *Occupational Health and Safety Act* and *Chemical Hazards Regulation*, which include some forms of cancer. The *Public Health Act*'s requirements for notifiable diseases apply to communicable diseases only, but there is also a provision allowing the Chief Medical Officer to require, by written notice, reporting of any disease where is it advisable to keep the disease under surveillance.

The *Hospitals Act* contains a confidentiality provision, but this provision does not apply to the cancer registry (pursuant to a provision in the *Cancer Programs Act*).

Registration of death and completion of medical certificates specifying the cause of death according to the international classification are required by the *Vital Statistics Act*. The Act gives permission for publication of statistical information but otherwise communication of information is prohibited. All records etc. are the property of the Crown. The *Statistics Bureau Act* sets out the duties of the Alberta Bureau of Statistics, allows agreements to be made with any federal department for the collection, transmission and exchange of information or statistics, and requires secrecy. Statistics must not be published that will allow individuals to be identified.

The Alberta *Freedom of Information and Protection of Privacy Act* has applied to health care bodies since 1998. It contains the usual provisions for access, collection, use and disclosure. A new piece of legislation, the *Health Information Act*, was passed in December 1999 and is expected to be proclaimed in force later this year. Both apply to the Alberta Cancer Board but are subject to the *Cancer Programs Act* and its regulations, which are paramount. The *Health Information Act* covers a scope of provisions similar to the *FOIPPA*, but contains some additional provisions specific to health information, including more extensive provisions governing disclosure for research; disclosure among health information custodians; and, in other circumstances, provisions on data matching and electronic disclosure. The Act requires custodians to collect, use and disclose the minimum amount and the most anonymous form of information possible to achieve the purposes.

4.03.4 SASKATCHEWAN

The cancer registry in Saskatchewan is governed by the *Cancer Foundation Act*. The Foundation is required to keep a register of patients, defined as those "afflicted with cancer." Physicians, dentists and hospital administrators are required to provide any requested information to the Foundation. The Foundation may make regulations regarding the registration of patients; however, no such regulations were found.

The *Public Health Act, 1994* regular reporting requirements deal only with communicable diseases, but the Minister may also specify any deaths, injuries, symptoms, syndromes or diseases that must be reported.

The Minister of Health is responsible for investigating the causes of disease and for collecting and disseminating information and statistics on health matters.

Currently, the Cancer Foundation is subject to the *Local Authorities Freedom of Information and Protection of Privacy Act*, and other public bodies would be subject either to this Act or to the *Freedom of Information and Protection of Privacy Act*. However, a new health information statute, the *Health Information Protection Act*, was passed in 1999, although it is not yet in force. The "trustees" covered by the *Health Information Protection Act* will include the Cancer Foundation. Saskatchewan also has a *Privacy Act* allowing tort actions for breach of privacy.

The *Department of Health Act* and *Saskatchewan Medical Care Insurance Act* contain confidentiality provisions. The latter Act allows disclosure of information to the Cancer Foundation.

The *Statistics Act* gives authority to the director to collect, compile, analyze and publish statistical information and to collaborate with or assist government departments with these activities. Employees are sworn to secrecy except for permitted disclosures and sharing of information, for example with Statistics Canada. The *Vital Statistics Act, 1995* contains the requirements for registration of death and cause of death according to the International List of Causes of Death. The information obtained under this Act must remain confidential except for the release of statistical, non-identifying data.

The Cancer Foundation provided copies of two of its policies on access to information: SCF Policy No. DS-01, "Information for Research and Statistics (Staff)" and SCF Policy No. DS-02, "Information for Research and Statistics (Non-Staff)." Policy No. DS-01 applies to access to registry data by staff of the Foundation for research, but not for clinical or administrative purposes; DS-02 applies to any individuals not part of the Foundation's staff. If identifiable information is sought by staff, a written request explaining the nature of the research or request must be provided. In both policies, statistical information "will be provided without restriction provided there is not sufficient data to identify an individual." If identifiable information is sought, the Director of Data Services, in consultation with the Director of Cancer Epidemiology and the Clinic Director(s), will decide whether the request will be accepted. Under DS-02, non-staff who are given access to data must sign a contract that includes the following guarantees:

I. The information will be stored securely and access will be limited to those involved with the project.
II. The information will not be used for any purpose other than that authorized.
III. The information will not be duplicated for any other purpose than this project.
IV. The information will be destroyed or returned when the study is complete.
V. Any research reports or publications will contain no identifying information.
VI. Copies of reports or publications will be made available to the Saskatchewan Cancer Foundation.
VII. Any report or publication will acknowledge the source of the data.
VIII. Any other items that may be appropriate.

Where a patient will be contacted by non-staff researchers, the Foundation will obtain written permission from the patient prior to releasing the information.

DS-02 also contains a section on funding and costs; generally, funded projects will be charged for the costs incurred in servicing the project.

4.03.5 MANITOBA

The *Cancer Treatment and Research Foundation Act* sets out the objects of the Foundation including research and "the adequate reporting of cases of cancer and the recording and compilation of data relating to cancer."

Reporting requirements are set out in regulations under the *Public Health Act*. The regulations define reportable disease as "cancer or malignant neoplasm" in addition to listed communicable diseases. A specific provision requires reporting of cancer or malignant neoplasm by health professionals "without delay" and on the form specified by the regulations. This form is addressed to the cancer registry at the Foundation. In addition, any death as a result of a reportable disease must be reported to the director or medical officer of health by the treating medical practitioner or hospital. Evidence of reportable diseases discovered by biopsy or autopsy must also be reported. The medical officer must keep a record of reports received and forward the information to the director within 24 hours. Under the Act, any failure to comply with the Act or regulations is an offence punishable by a fine of up to $5,000 or three months' imprisonment. The *Public Health Act* also contains a prohibition on the sale of biological products obtained free of charge or through the Minister.

The *Department of Health Act* also gives authority to the Minister to collect and disseminate information and statistics on health matters. The *Statistics Act* gives authority to the bureau to collect, compile, analyze, abstract and publish statistical information and collaborate with government departments for these purposes. The director and employees must take an oath of secrecy, and unauthorized access or disclosure is prohibited. Information may be shared with, for example, other departments, Statistics Canada or others with consent.

The *Vital Statistics Act* requires registration of death and certification of cause of death according to the international list. Access to information is prohibited except for statistical data or for research or statistical purposes with the consent of the director. The director may provide information for "bona fide research or statistical purposes" where the purpose cannot reasonably be achieved without identifiable information and where a written undertaking not to disclose identifiable information is received. All records are the property of the Crown.

Although Manitoba also has a *Freedom of Information and Protection of Privacy Act*, the *Personal Health Information Act*, in force since 1997, applies to personal health information in the hands of "trustees" including health professionals, health care facilities, public bodies or health services agencies. The Foundation is included as a health care facility. A regulation under this Act contains provisions on security policies, safeguards for electronic information, access by employees and pledges of confidentiality for employees. The *Privacy Act* allows an action in tort for violation of privacy. This Act applies notwithstanding any other and prevails over other legislation. However, it is a defence to an action if the defendant acted under the authority of another law.

CancerCare Manitoba has a form for requesting information from the Registry, which contains a section on relevant ethics committee approvals and an agreement to abide by the policy on release of information. Applicants are required to describe safeguards for storage and methods for the

destruction of information. Copies of reports must be forwarded for review prior to publication. There is also a "Disclosure of Personal Health Information for Research Agreement," which contains provisions on the purpose for which information will be used, prohibition on releasing information, secure storage, return/destruction of information or rendering it anonymous, prohibition on publication of identifying data, provision of papers before and after publication, and acknowledgement of the source of data in any publication. Employees and others having association with CancerCare Manitoba are also required to sign a "Personal Health Information Pledge of Confidentiality."

The Foundation has adopted a series of policies as part of its Administrative Policy and Procedure Manual which implement provisions of the *Personal Health Information Act*. A document dated February 1998 called "Manitoba Cancer Care Network Personal Health Information Policies and Procedures" is intended to ensure that use and operation of the computer system being delivered by the Manitoba Cancer Care Network (MCCN) Project comply with the *Personal Health Information Act*.

4.03.6 ONTARIO

In Ontario, the Cancer Treatment and Research Foundation, now called Cancer Care Ontario (CCO), is governed by the *Cancer Act*. This Act sets out the objects of CCO, including reporting of cases, recording and compiling of data, and public education. CCO may enter into agreements for carrying out these objects. The Act provides that information and reports provided to CCO will be kept confidential and provides protection from liability for practitioners or hospitals who provide information to CCO.

The reporting requirements under public health legislation (*Health Protection and Promotion Act*) do not include cancer. The Act lists prevention and control of cancer as one of the functions of boards of health but does not provide for reporting or surveillance specifically.

CCO is one of the bodies permitted, pursuant to the *Health Cards and Numbers Control Act* and its regulations, to collect or use health numbers for purposes related to health research or epidemiological studies.

Under the *Hospital Management Regulation* (under the *Public Hospitals Act*), there is a general confidentiality provision, but hospitals are required to provide, upon request from the Minister, information from medical records and x-ray films to CCO and information from medical records to any person for the purposes of "information and data collection, organization and analysis." A regulation under the *Independent Health Facilities Act* also allows information to be provided to CCO, but this appears to apply only to non-identifying information.

The Minister is authorized under the *Ministry of Health Act* to initiate, promote, conduct and maintain research programs, and to collect or publish information and statistics on health matters. Under the *Statistics Act*, a minister authorized by the Lieutenant Governor in Council may collect, compile, analyze and publish statistical information and enter into agreements with other governments and agencies for this purpose. An oath of secrecy is required of anyone collecting statistics, and disclosure of information is prohibited without permission. The *Vital Statistics Act* requires registration of death, and all deaths registered will be classified by the Registrar General. The Act allows publication of statistical information that does not identify individuals.

Ontario has a *Freedom of Information and Protection of Privacy Act*, but this Act does not currently apply to CCO. A draft *Personal Health Information Protection Act* was released in 1997; to date no such legislation has been enacted in Ontario.

Information available on CCO's internet site[87] confirms that cancer is not a reportable disease in Ontario but that CCO maintains a cancer registry pursuant to its statutory authority (the *Cancer Act*). The registry is a computerized database of information on all Ontario residents newly diagnosed with cancer or who have died of cancer. The major data sources are hospital discharge summaries, pathology reports, patient records from cancer treatment institutions, and death certificates. Information is regularly contributed to the Canadian Cancer Registry (Statistics Canada), the Public Health Branch of the Ministry of Health and international organizations.

CCO has a Procedures Manual for "Access to Information from the Ontario Cancer Registry for Research Purposes." It sets out criteria similar to those contained in the *Freedom of Information and Protection of Privacy Act* for allowing access to personal health information for research. It notes that although CCO does not currently fall within *FOIPPA*, it may soon be covered by similar legislation and some of its data derive from bodies that are subject to *FOIPPA*. The Procedure Manual discusses various types of requests of different levels of sensitivity.

The application package for "Access to Information from the Ontario Cancer Registry for Research Purposes" contains a procedures document, research application/agreement, confidentiality agreement, pledge of confidentiality and cost agreement.

4.03.7 QUEBEC

There is no legislation dealing specifically with cancer surveillance in Quebec. The *Public Health Protection Act* contains reporting requirements for prescribed diseases, but these do not currently include cancer. The Ministry of Health and Social Services (Ministère de la santé et des services sociaux) has general authority for research, collection and publication of information regarding health under various statutes; regional boards and the public health director also have authority under the *Act Respecting Health Services and Social Services*, which includes public health and surveillance functions.

The *Public Health Protection Act* requires any person operating a laboratory or an organ or tissue bank to hold a permit issued by the Minister of Health. Requirements regarding death certificates are also contained in this Act.

The province of Quebec has the most developed privacy legislation of any Canadian jurisdiction. In addition to the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*, which applies to public bodies including government departments and agencies, and health institutions, Quebec has the *Act Respecting the Protection of Personal Information in the Private Sector* and is the only province with such legislation. The Quebec *Charter of Human Rights and Freedoms* also protects the right of an individual to "the safeguard of his dignity, honour and reputation," to "respect for his private life" and to "non-disclosure of confidential information." It further provides that "[n]o person bound to professional secrecy by law ... may, even in judicial proceedings, disclose confidential information revealed to him by reason of his position or profession, unless he is authorized to do so by the person who confided such information to him or by an express provision of law."

Health administration statutes such as the *Hospital Insurance Act* and the *Act Respecting Health Services and Social Services* also have provisions on confidentiality and disclosure of information. The *Act Respecting Health Service and Social Services* buttresses the confidentiality of health

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[87] http://www.cancercare.on.ca/ocr/Welcome.html

information by requiring explicit consent from the patient for access. In addition, the *Code of Ethics of Physicians* governs the physician whether in hospital or a private office and is in regulation pursuant to the Act by force of law. Medical files in the office of a private physician are subject to the *Professions Code*, which requires all professional corporations to adopt a code of ethics. The *Medical Act* states that physicians may not be compelled to disclose information revealed to them in their professional capacity. These statutes reinforce article 9 of the Quebec *Charter* concerning the quasi-constitutional duty of professional secrecy. Finally, article 35 of the *Civil Code* of Quebec, adopted in 1994, enunciates the right to privacy of the person and also provides recourse to an aggrieved patient in the case of treatment outside of the public hospital.

With respect to research, consent (including record searches) must be free, informed and given in writing, according to the *Civil Code* and the recent amendments to the *Act Respecting Health Service and Social Services*. Such consent is valid only for the period of time approved by the ethics committee. An exception to this would be those situations in which the director of professional services authorizes access without patient consent, according to the legislation governing access to documents held by public bodies. The researcher would have to demonstrate that

(1) the intended use is not frivolous and the ends contemplated cannot be achieved otherwise; and
(2) such nominal information will be used in a manner that ensures confidentiality.

These additional conditions of ethics approval and a determined period of time were recently (in January 2000) adopted into law following a recent case in which access to medical records was provided and several years later the researcher wished to continue working with the patient records.[88]

The Quebec Ministry of Health and Social Services has published a document[89] that describes the operation of the registry, transfer of data to the Canadian Cancer Registry and the rules of the Fichier des tumeurs. Another Ministry guide deals with access to nominative data consistent with the *Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information*.

The registry obtains information from hospitals regarding the diagnosis of cancer in the case of hospitalization or day surgery.[90] Reporting by hospitals is said to be mandatory, although no legislative or regulatory requirement exists.[91] Agreements for the exchange of information with other provinces allow the collection of information on residents of Quebec who are treated outside the province. The registry is seeking to add to its data set information on outpatients and from laboratories, vital statistics (deaths) and health insurance information.[92] Currently, only information

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[88] *Parent v. Maziade*, [1998] A.Q. no 1867 (Que. C.A.). In this case, as a result of the merger of two hospitals, the records had been moved and the new director of professional services considered that the consent was no longer valid. The Quebec Court of Appeal maintained that confidentiality was "relative" and existed for the benefit of the patient. Since one of the aims of the research in question was to find the cause of susceptibility to manic depression and schizophrenia, the researcher needed access to the records for the purposes of familial recruitment.

[89] Ministère de la Santé et des Services sociaux du Québec, *Fichier des tumeurs du Québec (Système J665)* (Québec, PQ: Ministère de la Santé et des Services sociaux du Québec, 1998).

[90] *Ibid.* at 2.

[91] Confirmed by letter from Michel Beaupré, Responsable du Fichier des tumeurs du Québec, to Barbara von Tigerstrom, Health Law Institute, University of Alberta (27 January 2000).

[92] *Fichier des tumeurs du Québec*, *supra* note 91 at 2.

on the primary site of cancer is recorded, and no information is collected on progression of the disease or treatment, although the addition of this information is contemplated.[93]

4.03.8 New Brunswick

There is no specific cancer statute in New Brunswick. The *Public Health Act* allows notifiable diseases, injuries and risk factors to be prescribed by regulation, but cancer is not currently prescribed as a notifiable disease.

A regulation under the *Hospitals Act* requires information to be kept confidential with certain exceptions, including information for approved scientific research, upon direction by the Minister or upon the written request of a person designated by the Minister. The *Medical Services Payment Act* has a similar provision requiring secrecy except as provided, including disclosure of non-identifying information and disclosure of identifying information to designated bodies for health research and epidemiological studies.

The New Brunswick Statistics Agency has authority under the *Statistics Act* to collect, compile, distribute, etc. statistical data and collaborate with government bodies for these purposes. The Director and employees are required to swear an oath of secrecy and information must be kept confidential except as permitted under the Act. The Minister may enter into agreements with Statistics Canada and other bodies for collection or sharing of information.

The *Vital Statistics Act* requires registration of death and certification of cause of death. Unlike other provinces, New Brunswick's Act and regulations do not refer to international classifications of cause of death. Information is confidential, but publication of statistical data is permitted.

New Brunswick has not had privacy legislation in place but has instead used a code of practice; however a new *Protection of Personal Information Act* is expected to come into force in the spring of 2000. This Act makes compliance with the Statutory Code of Practice mandatory for public bodies. The Code is based on the Canadian Standards Association Model Code.[94] The COACH guidelines[95] have been adopted as the standard for New Brunswick's Department of Health and Community Services.[96] A *Right to Information Act* also exists. It gives a right of access to information about public business, but excludes personal information about another person.

4.03.9 Prince Edward Island

There is no specific statute for cancer, but cancer ("malignant neoplasm") is a notifiable disease under the *Public Health Act* and regulations. Any incidence must be reported to the Chief Health Officer. A cancer registry is maintained in the Oncology Department of the Queen Elizabeth Hospital. New primary sites of cancer are registered and coded according to the International Classification of

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[93] *Ibid.* at 1.

[94] Canadian Standards Association *Model Code for the Protection of Personal Information*, CAN/CSA-Q830-96 (Etobicoke, Ontario: Canadian Standards Association, 1996).

[95] Canadian Organization for Advancement of Computers in Health, *Security and Privacy Guidelines for Health Information Systems* (Edmonton, Alberta: Healthcare Computing and Communications Canada, Inc., 1995).

[96] Telephone conversation with Valerie Haggerman, Department of Health and Community Services (28 February 2000).

Diseases. Mortality data are taken from death certificates.[97]

The *Public Health Act* also gives the Minister the responsibilities of carrying out and encouraging data collection and analysis on health matters and programs of education, research and information relating to disease and public health. The Act requires information to be kept confidential by employees but allows disclosure of reports or statistical compilations, or other information in the public interest, as long as identifiable personal health information is not disclosed.

Under the *Hospital and Diagnostic Services Insurance Act* and the *Health Services Payment Act*, the P.E.I. Health and Community Services Agency (formerly Hospital and Health Services Commission) has the power to conduct surveys and research programs and to obtain statistics relating to health services. These two Acts require employees of the Agency to maintain secrecy of information subject to certain exceptions (none of which are directly relevant to cancer surveillance). Under the *Health Services Payment Act*, non-identifying statistical data may be released. The *Hospital Management Regulations* under the *Hospitals Act* prohibit the removal, inspection or release of information from medical records, with certain exceptions, including approved scientific research by members of medical staff or designated officers or employees, compilation of statistics, and medical and epidemiological research.

The *Provincial Health Number Act* allows certain persons to collect and use provincial health numbers, including persons prescribed by the regulations for research or epidemiological studies.

Prince Edward Island does not have freedom of information or privacy legislation. A bill was tabled in 1997 but did not progress past first reading.

The *Vital Statistics Act* contains the usual provision on registration of death and certification of cause of death according to the international classification. Information must not be disclosed except in statistical form or, as permitted by the regulations, to other government officials (of P.E.I., other provinces or the federal government), as required for official duties.

4.03.10 Nova Scotia

Provisions for reporting of cancer are contained in the *Health Act*. Medical practitioners, hospital administrators and any other persons or agencies required by the Minister must report diagnosis or treatment of cancer to the Cancer Treatment and Research Foundation or other designated person. The Commissioner of Cancer Care Nova Scotia has recently been designated as the person to whom reports should be made.[98] The report must be on the prescribed form and submitted within 10 days of the diagnosis being established. These reports are confidential and may only be disclosed in the course of administration of the Act.

The former *Cancer Treatment and Research Foundation Act* was repealed by the *Queen Elizabeth II Health Sciences Centre Act*, which amalgamates the Foundation with other bodies, creating the Queen Elizabeth II Health Sciences Centre. The Centre is responsible for operating a hospital along with research and other facilities. The *Cancer Treatment and Research Foundation Act* had a more detailed description of the Foundation's responsibilities, including explicit authority for a central

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[97] L. D. Van Til & D. Dryer, *Cancer Trends in Prince Edward Island 1983-1997* (Charlottetown: Queen's Printer, 1997) at 3-4.

[98] Telephone conversation with Maureen McIntyre, Nova Scotia Cancer Registry, (27 March 2000).

registry; there is no comparable provision in the new Act (the general provision in the new Act could be read as including all of the previous objects). There is also a Health Research Foundation established by statute, which is responsible for assisting with and funding health research and studying matters as requested by the Minister.

The *Hospitals Act* and *Health Services and Insurance Act* contain confidentiality provisions. The former Act provides that records will nevertheless be available to, *inter alia*, persons or agencies authorized by law or designated by the Minister, or to the Minister. The latter allows disclosure pursuant to the *Freedom of Information Act* or as prescribed by the Minister. The confidentiality provisions in the *Hospitals Act* take precedence over the *Freedom of Information and Protection of Privacy Act* in the event of a conflict.[99]

The Nova Scotia Statistics Agency is empowered under the *Statistics Act* to collect, analyze, publish etc. statistics and collaborate with departments for that purpose. An oath of secrecy is required, and identifiable information may not be disclosed except as authorized by the Minister or Director. Agreements may be made for sharing information with Statistics Canada or other bodies. The *Vital Statistics Act* requires registration of deaths and certification of cause of death according to the International List of Causes of Death. It allows publication of statistical information but prohibits any other communication of information to unauthorized persons.

Nova Scotia has a *Freedom of Information and Protection of Privacy Act,* which applies to public bodies; however, the cancer registry is not specifically covered by the Act.[100] Regulations under the Act set out the conditions that must be included in an agreement for disclosure of personal information for research purposes.

4.03.11 NEWFOUNDLAND

The *Cancer Treatment and Research Foundation Act* sets out the objects of the Foundation including "the adequate reporting of cases of cancer and the recording and compilation of data relating to cancer." Cancer is defined to include "all forms and types of malignant growth and precancerous conditions."

The *Public Health Act* does not set out specific reporting requirements but contains a general provision requiring public institutions, medical practitioners, nurses, dentists and others to collect and provide information on matters affecting public health as requested by the department.

The Foundation is covered by the *Freedom of Information Act,* but this Act does not allow access to personal information regarding identifiable individuals, with certain exceptions, including authorization under another law. There is no other statute on protection of personal information in the hands of government bodies. The *Privacy Act* provides for a right of action in tort for violations of privacy.

Under the *Medical Care Insurance Act*, information must be kept secret subject to certain exceptions, including disclosure authorized by another statute or disclosure to a person engaged in health or medical research, at the discretion of the Minister. Where information is disclosed for research, the recipient may not publish or disclose the information if it would be detrimental to the personal interest

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[99] *Ibid.*

[100] *Ibid.*

or privacy of the subject. A regulation under this Act allows information to be released in accordance with a policy adopted by the Newfoundland Medical Care Commission and approved by the Minister.

The *Hospitals Act* contains similar provisions. Hospitals must not allow disclosure or access to information in hospital records except as stated; disclosure is permitted to a government agency or department where approved by the Minister. Access for research is permitted if the research is in the public interest and the person engaging in the research understands the provisions on disclosure. These prohibit disclosure or publication of information where it could be detrimental to the personal interest, reputation or privacy or a patient, physician, staff member or employee. Breach of this prohibition is an offence carrying a fine of up to $500.

Under the *Department of Health Act*, the Minister is responsible for supervising registration of vital statistics, for collecting information and statistics relating to public health, disseminating information to promote health, and issuing reports, statistics, circulars or other information in relation to public health. The *Vital Statistics Act* requires registration of all deaths and certification of cause of death. The Statistics Agency, established by statute, is authorized to collect, compile, etc. statistical information and to collaborate with departments for this purpose. The Minister may enter into agreements with statistical agencies of other governments for the exchange of statistical information, but only where the other agency has statutory authority and is subject to similar prohibitions and penalties for disclosure of information. The director and employees of the Agency must swear an oath of secrecy, and information may not be disclosed in identifiable form subject to certain exceptions. Regulations under this Act allow information to be released to Statistics Canada pursuant to agreements between the Newfoundland and federal governments.

Although Newfoundland does not have comprehensive legislation for the protection of personal information or health information, policies on privacy and confidentiality are being developed. A study was completed by the Institute for Advancement of Public Policy[101] and a committee is being struck for implementation of the recommendations.[102] If these policies are accepted for use in the government the Cancer Treatment and Research Foundation will be guided by them.[103]

4.03.12 Northwest Territories and Nunavut

Legislation in the Northwest Territories and Nunavut is essentially identical as Nunavut has adopted Northwest Territories statutes and regulations (with a few exceptions as noted in the table in Appendix A).

The *Disease Registries Act* requires health professionals who examine, diagnose or treat persons with reportable diseases to provide specified information to the Registrar of Disease Registries. Additional information may also be requested. Currently, the regulations define malignant neoplasms (ICD nos. 140-208), carcinoma *in situ* (ICD nos. 230-234) and "neoplasms of uncertain behaviour or unspecified nature" (ICD nos. 235-239) as reportable diseases. The Act also provides for reporting requirements for "reportable tests," but currently there are no reportable tests specified in the

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[101] Institute for the Advancement of Public Policy, *Privacy and Confidentiality Policies and Procedures Project: Final Report* (Newfoundland Department of Human Resources and Employment, Department of Health and Community Services, 1999).

[102] Letter from Bertha H. Paulse, Newfoundland Cancer Treatment and Research Foundation to Barbara von Tigerstrom, Health Law Institute, University of Alberta (25 January 2000).

[103] *Ibid.*

regulations.

The Registrar is required to maintain a register for each reportable disease (or test). The information provided to the Registrar must be kept confidential, and the register or information may not be examined except as provided in the Act. The Minister, Registrar, Deputy Minister and persons designated by the Minister may review a register for various purposes, including preparation of accurate estimates of incidence and identification of patterns of reportable diseases. Information may also be disclosed as necessary for the treatment of the individual who is the subject of the information or under agreements with the Government of Canada or another province or territory. Statistical information may be released to persons from other jurisdictions by application. Persons may also apply for access to the registry information for medical, epidemiological or other research. Access may be given if certain criteria are met; a person who is given access for research is subject to certain restrictions and duties under the Act with respect to confidentiality and publication.

The Minister also has general authority under the *Hospital Insurance and Health and Social Services Administration Act* to conduct surveys and research programs and to obtain statistics for these purposes.

The Territories have an unusual piece of legislation (the *Scientists Act*) which requires any person carrying out scientific research (except wildlife or archaeological work) or collecting specimens for scientific research to obtain a licence. A permit requirement in the *Medical Profession Regulations* applies only to clinical research by medical practitioners.

The *Hospital Standards Regulations* require medical records of in-patients and out-patients to be kept secret and disclosed only as permitted, including disclosure to other hospitals or other facilities (including cancer clinics) as required for proper care, diagnosis and treatment; for academic purposes by medical staff; or as directed by the Territorial Hospital Insurance Services Board. There are also confidentiality provisions in the *Medical Care Act*, which require information with respect to insured services to be kept confidential. Information may be disclosed by the Director to a person engaged in *bona fide* scientific research provided the information is not published or otherwise made public except as approved by the Director and in non-identifiable form.

The *Vital Statistics Act* provides for registration of deaths and medical certificates stating the cause of death according to the International List of Causes of Death. Information must not be disclosed except in statistical form, and all records and other documents are the property of the Crown. The Chief Medical Health Officer and his or her staff are authorized under regulations to have access to vital statistics records to gather statistics for public health purposes. They are required to swear an oath of secrecy.

The *Access to Information and Protection of Privacy Act* applies to public bodies and contains provisions on collection, use and disclosure of personal information. Regulations under the Act prescribe the contents of agreements for disclosure of information for research purposes.

4.03.13 FEDERAL

Under the *Department of Health Act*, the federal Minister of Health has the authority and duty to promote and preserve the health and well-being of the people of Canada and specifically to investigate and conduct research into public health, "including the monitoring of diseases," and to collect, analyze, interpret, publish and distribute information relating to public health. He or she may cooperate with provincial authorities to coordinate public health efforts.

Federal government institutions are subject to the *Access to Information Act* and the *Privacy Act*. The latter deals with collection, use and disclosure of personal information.

Part 1 of Bill C-6 (formerly Bill C-54), the *Personal Information Protection and Electronic Documents Act*, will protect personal information in the private sector, beginning with federally regulated industries and gradually expanding to include all private sector commercial activities unless an equivalent provincial law is in place. The provisions for protection of personal information are based on the Canadian Standards Association Model Code. The Bill's application to personal health information has been the subject of considerable controversy,[104] and debate continues as to whether, or to what extent, Part 1 applies or should apply to health information. The Bill has been returned to the House of Commons with an amendment recommended by the Senate to delay the Bill's application to health information for an additional year after the Act comes into force. The Minister of Industry moved adoption of the amendments on February 7, 2000.[105]

The federal *Statistics Act* is very important, since the Canadian Cancer Registry is maintained within the Health Statistics Division of Statistics Canada. Under the Act, Statistics Canada has the duty to collect, compile, analyze, abstract and publish statistical information and to collaborate with government departments for these purposes. It is specifically directed to collect, compile, etc. information on certain matters, including health. The Chief Statistician, employees and contractors are required to take an oath that includes non-disclosure. There is also a prohibition on disclosure of identifiable information subject to certain exceptions, and contravention of this prohibition is an offence under the Act.

The Minister may enter into agreements and arrangements with provincial governments for exchange of information and other matters, and with departments, municipalities and corporations for sharing of information. Information may be disclosed under these agreements and in other specified cases, including disclosure with consent or disclosure of information relating to any hospital or other non-commercial institution as long as the information cannot be related to any individual patient or other person. Persons having the custody or charge of any documents or records maintained in any department, municipal office, corporation, business or organization must grant access for the purposes of the Act.

Statistics Canada's Policy Manual covers external relations; content of product; dissemination of products; confidentiality, security and privacy; and internal management. The section on dissemination includes Policy 3.1, "Policy on Publishing and Publications." The section on confidentiality, privacy and security includes the following:

- 4.1 Policy on Record Linkage
- 4.2 Policy on Microdata Release
- 4.3 Discretionary Release Policy
- 4.4 Security Policy for the Government of Canada
- 4.5 EDP Security Policy
- 4.7 Security of Sensitive Statistical Information

We reviewed one example of an agreement for data sharing with Statistics Canada. CancerCare

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[104] See B. von Tigerstrom, "The 'Hidden Story' of Bill C-54: The *Personal Information Protection and Electronic Documents Act* and Health Information" (1999) 8:2 Health L. Rev. 13.

[105] See Industry Canada, "Update on Privacy Legislation" online: <http://e-com.ic.gc.ca/english/privacy/632d1.html>.

Manitoba provided a copy of the "Agreement Concerning Cancer Registry Data" between the Government of Canada and the Government of Manitoba, which deals with sharing of information between the provincial registry and Statistics Canada (National Cancer Registry). The Agreement covers

- provision of information to Statistics Canada by the Foundation
- use of the information by Statistics Canada
- confidentiality and protection
- national requirements, including agreements with other provinces and establishment of an advisory committee
- obligations with respect to transmission of data (in Appendix B)
- release of information by Statistics Canada (in Appendix C)

Appendix B of the Agreement sets out the respective responsibilities of Statistics Canada and Manitoba's Department of Health. Appendix C contains provisions on access to and release of data from the National Cancer Registry (Statistics Canada). These provisions are similar to those for access to the provincial registry. In addition they state that information reported from a provincial registry can be returned freely as long as it has not been linked to other Statistics Canada files and does not contain information derived from such linkage; and that Statistics Canada will inform the directors of provincial registries of any request for data and ask them to approve in writing use of the data they provided to Statistics Canada. A Policy Committee at Statistics Canada will review any request for scientific merit.

The document on the Quebec cancer registry also discusses information sharing with the Canadian Cancer Registry at Statistics Canada. Data are transmitted annually once all registrations for the year are received and processed, death registrations are available for the year in order to update the data on deaths, and new cases from other provincial registries are registered and validated. The document contains technical standards on how to convert files for transmission to the Canadian Cancer Registry.[106]

4.04 Analysis of performance criteria

Relevant performance criteria were identified in Appendix C of the Request for Proposals that guided development of this legislative review (attached to this report as Appendix X). The legislation in place in each jurisdiction was considered with reference to these criteria. For convenience, a summary of cancer-specific provisions in each jurisdiction relevant to the criteria is attached as Appendix B. This section reviews legislative requirements only, and not the actual practices of registries that may be established by internal policies and procedures. In addition, it focuses on cancer-specific legislation, although the relevance of other types of legislation is noted where appropriate.

4.04.1 Sources of data

REPORTING REQUIREMENTS

Alberta, Manitoba, P.E.I., Nova Scotia, the Northwest Territories and Nunavut have routine mandatory reporting requirements. British Columbia and Saskatchewan require information to be supplied only upon request. They are included in this section as relevant. Other jurisdictions, e.g. Ontario, maintain a registry without having any mandatory reporting requirement.

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[106] *Fichier des tumeurs du Québec, supra* note 91 at 81-88.

REPORTING OBLIGATIONS ARE IMPOSED ON:

- physicians/medical practitioners (Alberta, Saskatchewan, Manitoba, Nova Scotia)
- health care professionals (Manitoba, NWT/Nunavut)
- dentists (Saskatchewan)
- persons responsible for laboratories (Alberta)
- persons responsible for hospitals or health facilities (Saskatchewan, Manitoba, Nova Scotia, NWT/Nunavut)
- any person performing a biopsy or autopsy (Manitoba)
- any person (B.C.)
- undefined (P.E.I.)

THE REPORTABLE CONDITIONS ARE DEFINED AS:

- cancer, as defined by the "list of all diseases classified as malignant, in situ or metastatic in the International Classification of Diseases for Oncology, as amended from time to time, published by the World Health Organization" (Alberta)
- "all forms and types of malignant and premalignant conditions" (Saskatchewan)
- cancer or malignant neoplasm (Manitoba)
- malignant neoplasm (P.E.I.)
- cancer (undefined) (Nova Scotia)
- malignant neoplasms (ICD nos. 140-208); carcinoma in situ (ICD nos. 230-234); neoplasms of uncertain behaviour or unspecified nature (ICD nos. 235-239), using ICD-9 (NWT/Nunavut)

Therefore, only two jurisdictions refer to the ICD-9 classification in defining reportable cancers; the NWT/Nunavut legislation matches the recommended performance characteristics most closely.

THE EVENTS THAT MUST BE REPORTED ARE:

- patient with cancer (Alberta, Saskatchewan, Manitoba, Nova Scotia)
- patient suspected to have cancer (Alberta)
- specimen examined reveals cancer (Alberta, Manitoba)
- patient dies of cancer (Manitoba)
- "occurrence" of notifiable disease (P.E.I.)
- diagnosis of cancer (Nova Scotia)
- examination, diagnosis or treatment of a person with respect to a reportable disease (NWT/Nunavut)

There is some variation as to when the reporting requirement is triggered: it may include any patient with cancer (whether or not it is a new diagnosis), in one jurisdiction suspected cases, and in only one jurisdiction cancer deaths. None of the statutes reviewed defined residency requirements for reporting.

The information that must be provided may be defined in more or less detail. British Columbia and Alberta both have regulations setting out a detailed list of what must be reported. The NWT/Nunavut statute lists the information required. Saskatchewan requires any information requested; P.E.I. simply states that an "occurrence" must be reported. In Manitoba, Nova Scotia and NWT/Nunavut, a form for reporting may be specified by regulation, and this would to some extent determine the information that would be reportable.

REPORTING MUST BE DONE:

- as soon as practicable (Alberta)
- forthwith (Manitoba)
- within 10 days of diagnosis (Nova Scotia)

Not every jurisdiction with reporting requirements specifies when reporting must be done.

In Manitoba the medical officer of health is required to forward any reports to the director within 24 hours of receipt.

None of the statutes reviewed specified a starting reference date for reporting.

All of the reporting requirements reviewed here (including the B.C. and Saskatchewan requirements to report upon request) are mandatory.

THE FOLLOWING PENALTIES FOR FAILURE TO COMPLY WERE FOUND:

- fine not exceeding $2,000 and/or imprisonment not exceeding 6 months (B.C.)
- fine not exceeding $5,000 and/or imprisonment not exceeding 3 months (Manitoba)
- fine not less than $100 and not more than $500 (Nova Scotia)
- fine not exceeding $1,000 and/or imprisonment not exceeding 6 months (P.E.I.)
- fine not exceeding $500 and/or imprisonment not exceeding 30 days (NWT/Nunavut)

Nova Scotia's statute provides that each day that a person fails to comply is a separate offence.

COLLECTION OF DATA FROM OTHER SOURCES

This section will review provisions that give specific authority to cancer agencies to collect data. It should, however, be noted that in addition to these provisions or even in the absence of such provisions cancer agencies may be permitted access to data under other statutes with general provisions on access/disclosure of information.

As noted above, British Columbia and Saskatchewan require certain persons to provide information on cancer patients at the request of the cancer agency. Alberta and NWT/Nunavut, in addition to having routine mandatory reporting requirements, also specifically authorize the cancer agency to request any further information that is considered necessary. In NWT/Nunavut, this is specified as any necessary information regarding examination, diagnosis and treatment of the person who has the disease; the statute also specifically states that health care professionals must comply with requests for further information. The Alberta statute provides that the cancer registry may contain information from certain specified sources.

4.04.2 Management

ADMINISTRATION

In Alberta, Saskatchewan, Manitoba, Ontario, Newfoundland and NWT/Nunavut, the cancer agency or foundation is given specific authority to establish and/or maintain a cancer registry. In some other jurisdictions, another body (e.g. ministry of health) has statutory authority that could be read to include maintenance of a registry.

The Saskatchewan, Manitoba and Ontario statutes authorize the foundation to enter into agreements with certain bodies and persons to carry out its objectives. Other statutes allow agreements specifically for disclosure of information (see below).

SECURITY

None of the cancer-specific statutes reviewed contains provisions on security standards. Reference to security safeguards in FOIPP or health information legislation may be applicable to the provincial cancer body. In addition, some agencies have adopted non-binding codes or guidelines on security

(e.g. COACH Guidelines[107]).

DATA QUALITY

Specific provisions on data quality are also absent from the cancer statutes reviewed. Definitions of reportable cancers and events, and prescribed forms for reporting may provide some consistency in reporting. Provisions authorizing agencies to request information may also help to ensure completeness of data.

4.04.3 Confidentiality, access and use of data

Cancer agencies and other relevant bodies may be subject to FOIPP and/or health information legislation (although this is not necessarily the case). In addition, most of the cancer-specific legislation contains provisions on confidentiality, access and use of data.

The provisions state a general rule of confidentiality or non-disclosure, and then set out the circumstances in which information may be disclosed:

- for research purposes (B.C., Alberta, Ontario, NWT/Nunavut)
- in court proceedings (B.C.)
- under an agreement for disclosure of information (B.C., Alberta, NWT/Nunavut)
- for compiling statistics (B.C., Ontario)
- to the Minister or person designated by the Minister (Alberta, NWT/Nunavut)
- when required by law (Alberta)
- to the subject or his/her legal representative (Alberta)
- in statistical form (non-identifying) (Alberta, P.E.I.)
- to persons authorized by the regulations to receive information (Alberta)
- with the consent of the subject (P.E.I.)
- as directed by the Chief Health Officer in the best interest of the person or the public (P.E.I.)
- by employees in the performance of their duties (Nova Scotia)
- to a health care professional where necessary for treatment of the subject (NWT/Nunavut)
- statistical information to a person from a jurisdiction that has not entered into an agreement for disclosure, who has functions similar to the Registrar (NWT/Nunavut)

Alberta and NWT/Nunavut also contain provisions on the use of registry information. Alberta's Act states that information in the registry is to be used for the following purposes:

(a) to assess and improve the standards of treatment and care provided to cancer patients;
(b) to assist in the treatment and care of the person who is the subject of the information;
(c) to assist in cancer research, education and prevention;
(d) to compile statistics on cancer
and any other purpose specified by the Minister.

The NWT and Nunavut legislation states that the Minister, Registrar, Deputy Minister and other persons authorized by the Minister may use information in the register:

a) to prepare accurate estimates on the number of people in the Territories who have a reportable disease;
b) to identify patterns of a reportable disease;
c) to assist in determining ways to reduce the incidence of a reportable disease in the Territories; and
d) to assist in the development of programs and policies designed to improve the health of the residents of the Territories.

With respect to disclosure for research, the B.C. and Ontario statutes simply state that information

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[107] See *supra* note 97.

received regarding cases of cancer may be disclosed for medical research purposes. The B.C. provision specifies that information may be disclosed to a person engaged in medical research regardless of whether the person is engaged in research for the B.C. Cancer Agency.

Alberta's legislation states that information may be disclosed "to a person conducting bona fide research or a medical review if the disclosure is made in a manner that ensures the confidentiality of the information." The NWT/Nunavut provisions are the most extensive on this point. They require a person wishing access to registry information for medical, epidemiological or other research to apply to the Registrar on an approved form, stating his or her qualifications to conduct the research and the purpose for which the information is to be used, and providing any other necessary information. The Registrar may allow access if he/she is satisfied that the person is qualified to do the research and that it may benefit the residents of the Territories, and if the applicant pays a fee. A researcher who is allowed access to the registry information must use it only for the purposes stated in the application and must not disclose the identity of any subject, health care facility or health care professional. The Registrar must be provided with a copy of any material to be published, and the Registrar may require the person to include a disclaimer in any published material. Any published material must acknowledge the source of the information and any disclaimer required, and a copy must be sent to the Registrar.

Again it should be noted that in some jurisdictions the FOIPP or health information legislation may apply with respect to disclosure of information for research, at least to the extent that it is not inconsistent with cancer-specific legislation (e.g. in Alberta). These may include provisions similar to those in the NWT/Nunavut statute.

Agreements for disclosure of information are also specifically covered in several provincial statutes. The British Columbia provisions allow agreements between the B.C. Cancer Agency and a government, government agency or other organization engaged in medical research; the agreements must relate to medical research and provide for the disclosure of information and records. The NWT/Nunavut legislation allows the Minister to enter into agreements on behalf of the government with the Government of Canada or the government of a province or territory, relating to disclosure of information in the register. The Registrar is then permitted to disclose information in accordance with such an agreement. The Alberta provision is similar, allowing agreements with the Government of Canada or a province, but also with any person, relating to disclosure of information; in addition, it specifies that any such agreement must require the information disclosed to remain confidential.

The Alberta statute contains specific prohibitions and penalties with respect to disclosure. It prohibits any person from disclosing, reviewing or examining information unless disclosure is authorized under the relevant provision. Thus both the person allowing the disclosure and the person accessing information without authorization are targeted. Breach of these prohibitions is an offence punishable by a fine of up to $10,000. British Columbia, Nova Scotia, P.E.I. and NWT/Nunavut have general offence and penalty provisions for any contravention of the legislation, which have been described above in section 1.(a). The confidentiality provision in the Ontario statute does not appear to be backed up by any penalty.

4.04.4 Liability

The statutes in British Columbia, Alberta, Saskatchewan, Ontario and NWT/Nunavut provide protection from liability for providing information to the cancer agency or other relevant body under the statute.

4.04.5 Funding

The NWT/Nunavut legislation specifically provides that researchers must pay a fee for access to registry information. The other statutes do not have specific provisions, although in some cases another applicable piece of legislation (e.g. FOIPP or health information statutes) may allow for collection of fees for access to information. The statutes establishing cancer foundations contain provisions regarding the funding of the foundation generally (Alberta, Saskatchewan, Manitoba, Ontario and Newfoundland).

4.05 Summary and assessment

The variation among Canadian jurisdictions with respect to the structure and content of the legislation relevant to cancer surveillance is significant. This lack of consistency, in addition to the complexity of the legal regime in most jurisdictions, will likely be a barrier to understanding and to cooperation among jurisdictions.

Furthermore, no jurisdiction's legislation fully matches the performance criteria formulated by the Canadian Coalition on Cancer Surveillance, and in most cases there is a significant gap between the recommended provisions and existing legislation.

5.01 Codes and guidelines

In addition to the legislative structure, there are a number of other documents that are relevant to cancer surveillance design and practice. A comprehensive analysis of these documents is beyond the scope of this project, but this section will highlight some of the most important documents that should be considered in conjunction with legislation.

5.02 Canadian Medical Association

The Canadian Medical Association has produced a *Code of Ethics* for physicians and a *Health Information Privacy Code* which specifically deals with health information.[108] The *Health Information Privacy Code* affirms individuals' right to privacy and sets out rules for collection, use and disclosure of personal health information. It deals with primary purposes (related to the provision of care to the individual) and secondary purposes, which may be "legislated" or "nonlegislated" depending on whether they are conducted under legislative authority. The Code contains quite stringent requirements with respect to consent for disclosure. Generally, consent is required for any disclosure. Consent may be inferred for primary therapeutic purposes, and disclosure without consent may occur where permitted or required by legislation. The qualification, however, is that the legislation in question must meet the requirements set out in the Code.[109]

5.03 Tri-Council Policy Statement

The Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans[110] contains relevant provisions on confidentiality and disclosure of information, in particular on secondary use of data and data matching.

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[108] *Supra* note 41.

[109] *Health Information Privacy Code*, *ibid.*, Paragraph 3.4. The requirements are set out in Paragraph 3.6.

[110] Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (1998).

Secondary uses involving identifying information must be approved by a research ethics board (REB). Access to identifying information will be permitted if the researchers demonstrate that

(a) identifying information is essential to the research; and
(b) they will take appropriate measures to protect the privacy of the individuals, to ensure the confidentiality of the data, and to minimize harms to subjects; [and]
(c) individuals to whom the data refer have not objected to secondary use.[111]

Note that the third criterion assumes that the individuals have some knowledge and have had an opportunity to object regarding secondary use.

An REB may also impose the following conditions for access:

(a) the informed consent of those who contributed data or of authorized third parties must be obtained; or
(b) there must be an appropriate strategy for informing the subjects; or
(c) consultation must take place with representatives of those who contributed data.[112]

Researchers must obtain the REB's authorization to contact data subjects.[113] Finally, Article 3.6 requires REB approval of the "implications of approved data linkage in which research subjects may be identifiable."

5.04 CSA Model Code

The Canadian Standards Association *Model Code for the Protection of Personal Information*[114] contains a set of 10 principles for the protection of personal information. It is designed as a voluntary code to be adopted by private sector organizations. It has also been incorporated as a Schedule to Bill C-6 (the federal *Personal Information Protection Act*) and used as the basis for New Brunswick's new *Protection of Personal Information Act*.

The Model Code contains the following principles:

Principle 1 - Accountability	An organization is responsible for personal information under its control and shall designate an individual or individuals who are accountable for the organization's compliance with the following principles.
Principle 2 - Identifying Purposes	The purposes for which personal information is collected shall be identified by the organization at or before the time the information is collected.
Principle 3 - Consent	The knowledge and consent of the individual are required for the collection, use or disclosure of personal information, except where inappropriate.
Principle 4 - Limiting Collection	The collection of personal information shall be limited to that which is necessary for the purposes identified by the organization. Information shall be collected by fair and lawful means.

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[111] *Ibid.*, Article 3.3.

[112] *Ibid.*, Article 3.4.

[113] *Ibid.*, Article 3.5.

[114] *Supra* note 96.

Principle 5 - Limiting Use, Disclosure and Retention	Personal information shall not be used or disclosed for purposes other than those for which it was collected, except with the consent of the individual or as required by law. Personal information shall be retained only as long as necessary for the fulfilment of those purposes.
Principle 6 - Accuracy	Personal information shall be as accurate, complete, and up-to-date as is necessary for the purposes for which it is to be used.
Principle 7 - Safeguards	Personal information shall be protected by security safeguards appropriate to the sensitivity of the information.
Principle 8 - Openness	An organization shall make readily available to individuals specific information about its policies and practices relating to the management of personal information.
Principle 9 - Individual Access	Upon request, an individual shall be informed of the existence, use, and disclosure of his or her personal information and shall be given access to that information. An individual shall be able to challenge the accuracy and completeness of the information and have it amended as appropriate.
Principle 10 - Challenging Compliance	An individual shall be able to address a challenge concerning compliance with the above principles to the designated individual or individuals accountable for the organization's compliance.

5.05 COACH Guidelines

The Canadian Organization for Advancement of Computers in Health (COACH) has produced *Security and Privacy Guidelines for Health Information Systems*.[115] Although they deal with privacy and fair information practices generally, the main focus is on security, i.e. methods for protecting the confidentiality and integrity of data.[116] The Guidelines cover the following areas of security: administrative and organizational security, personnel security, physical and environmental security, hardware security, communications security, software security and operations security. It also provides a framework for "threat risk assessment."[117]

5.06 Canadian Institute for Health Information

The Canadian Institute for Health Information (CIHI) is an independent, not-for-profit organization with a mandate from the provincial ministers of health to develop and maintain a comprehensive health information system.[118] CIHI is leading the Health Information Roadmap initiative to modernize the Canadian health information system.[119] It has also been active in the development of health

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[115] *Supra* note 97.

[116] The Guidelines define security as "[t]he degree to which data, databases or other assets are protected from exposure to accidental or malicious disclosure, interruption, modification, removal or destruction." *Ibid.* at 91.

[117] *Ibid.*, Annex 1.

[118] Canadian Institute for Health Information, *Privacy and Confidentiality of Health Information at CIHI: Principles and policies for the protection of health information*, 2d ed. (Ottawa: Canadian Institute for Health Information, 1999).

[119] See e.g. *Health Information Roadmap: Responding to Needs*, *supra* note 26.

information policies. It has recently released a second edition of its policy document *Privacy and Confidentiality of Health Information at CIHI*.[120] The document sets out CIHI's own policies, but may be a useful reference for other health information custodians. Its guiding principles are based on those contained in the CSA Model Code: accountability, limiting collection, limiting use, limiting disclosure, consent, integrity, security, openness, individual access and challenging compliance.[121]

6.01 International agencies

Biomedical research is a task that requires international efforts. Cancer is, without a doubt, one of the diseases that most preoccupy the international community.[122] Cancer census began in early 1900 and the idea of creating cancer registries soon followed.[123] The need for co-operation gave rise to the creation of different networks and agencies promoting research on cancer and facilitating the sharing of knowledge and discoveries in treating and preventing cancer. These agencies have contributed to progress in their consideration of legal, ethical and social issues related to cancer. Furthermore, some of them are especially committed to the harmonization of all aspects pertaining to cancer research, including cancer registration. In this next section, we will identify some of the organizations committed to cancer research and cancer registries, beginning with international agencies and then turning to those at a national level.

6.02 International Agency for Research on Cancer (IARC) and the International Association of Cancer Registries

The International Agency for Research on Cancer (IARC) was created under the aegis of the World Health Organization. Canada has been a member of the IARC since its inception in 1965. Article 1 of the Statute creating the IARC states that its mission is to "[p]romote international collaboration in cancer research" and "serve as a means through which Participating States and the *World Health Organization*, in liaison with the *International Union against Cancer* and other interested international organizations, may cooperate in the stimulation and support of all phases of research related to the problem of cancer".[124] More precisely, the IARC is involved in the development and promotion of cancer research and prevention. It provides financial, methodological and material support for the creation of cancer registries where such support is needed. In return,

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[120] Canadian Institute for Health Information, *supra* note 120.

[121] *Ibid.* at 2-4.

[122] For example, the World Health Organization in *Global Strategy for Health for All by Year 2000* (Geneva: WHO, 1981, s. 7), reported that about one-fifth of all deaths in developed countries were due to cancer. In its *Global Policy Framework for Year 1996-2001* (Geneva: WHO, 1994), and *Ninth General Programme of Work Covering the Period 1996-2001*, Health for All Series No. 11 (Geneva: WHO, 1994), WHO sets cancer reduction of 15% for people under 65 as a goal for the year 2001. In 1998, the Executive Board established that prevention and treatment of non-communicable diseases was a priority for the WHO and its members (WHO, Director General, *Noncommunicable Disease Prevention and Control*, EB101/14, 1997, 101st Session, Provisional Agenda Item 10.4.).

[123] See G. Wagner "Cancer registration: Historical Aspects" in D.M. Parkin *et al.*, eds., *The Role of the Registry in Cancer Control* (Lyon, France: IARC 1985) at 3. The first cancer census was done in Germany and it is believed that the first cancer registry, still in operation, was created in Hamburg in 1929. See also O.M. Jensen *et al.*, *Cancer Registration Principles and Methods*, IARC Technical Report No. 95 (Lyon: IARC, 1991).

[124] Statue of the International Agency for Research on Cancer, World Health Organization, Approved by the 18th World Health Assembly on May 1965 (Resolution WHA 18.44). Pursuant to its article III and XI, the Statute entered into force on September 15, 1965. See in particular, section 1.

some countries forward data to a project of IARC called "Cancer Mondial," which provides worldwide epidemiological information on cancer. The IARC is also committed to cancer research and cancer prevention throughout the world.[125]

The International Association of Cancer Registries (hereinafter the "Association") is hosted by the IARC. It describes itself as "a professional society dedicated to fostering the aims and activities of cancer registries worldwide. It is primarily for population-based registries, which collect information on the occurrence and outcome of cancer in defined population groups (usually the inhabitants of a city, region, or country)".[126]

Over the years, the IARC, often in collaboration with the Association, has published literature on cancer registration that serves as a reference for the establishment, management and maintenance of cancer registries.[127] The IARC has also established guidelines on topics related to cancer registration. For the purposes of this study, a very important document is the "Guidelines on Confidentiality in the Cancer Registry".[128] This is used by many registries and has inspired the normative framework that governs the confidentiality of cancer registries around the world. It establishes the fundamental principles of confidentiality and advances guidelines for the use and release of registry data in accordance with these principles.[129]

Highlights of the guidelines may be summarized as follows. IARC recognizes that cancer reporting may be voluntary or mandatory. When cancer reporting is mandatory, the law should provide legal protection to the data supplier. The registry should clearly establish the purpose for which data are collected and registered. Confidentiality rules aim to strike a balance between the right to privacy of the individual and the right to benefit from cancer surveillance and scientific research in the treatment of cancer. The standards of confidentiality of a registry should be the same as those that apply to the doctor-patient relationship and should extend indefinitely (even after the patient's death). They should also satisfy the data suppliers (including the treating physician who usually has the primary responsibility for the confidentiality of information) that they will benefit from adequate protection. Indirectly identifiable data should be treated as identifiable data and handled with a high level of confidentiality.

Use of adequate security measures for storage and reliable means for transferring data are required. These measures include the maintenance of securely locked premises, the designation of staff members who may have access to personal data, restricted access to computer terminals and the establishment of any other measure required to ensure the security of the data. This responsibility lies

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[125] *Ibid.* s. 2.

[126] International Association of Cancer Registry. Online: <http://www-dep.iarc.fr/iacr/about.htm> (date accessed : 26 March 2000).

[127] See for example, O.M. Jensen *et al.*, *Cancer Registration Principles and Methods*, IARC Technical Report no. 95, (Lyon, France: IARC, 1991); *Multiple Primaries*, IARC Internal Report no. 94/003, (IARC, Lyon, February 1994) ; D. Esteban *et al.*, eds., *Manual for Cancer Registry Personnel*, IARC Technical Report no. 10, (Lyon, France: WHO & IARC 1995); D.M. Parkin *et al.*, *Comparability and Quality Control in Cancer Registration*, IARC technical Report no. 19, (Lyon, France: IARC, 1994).

[128] IARC & International Association of Cancer Registries, *Guidelines on Confidentiality in the Cancer Registry*, IARC Internal Report, No. 92/003, (IARC, Lyon, March 1992).

[129] *Ibid.*, Preamble.

with the director of the registry. The IARC also recommends that staff members sign a "special declaration of secrecy". They should also be educated and reminded of their duty of confidentiality.

Access to identifiable data should be given to treating physicians for clinical purposes but should generally be restricted to the patient (unless required by law). Identifiable data may also need to be communicated in two other cases: when the person diagnosed with cancer is a resident of another jurisdiction with its own registry (or a collaborating registry) or when a nationwide registry or specialized cancer registry requires the transmission of such data for the establishment of a national cancer surveillance program. The recipient registry should always adhere to comparable standards of confidentiality. A procedure should be established and documented for other types of requests for access to identifiable data. Such requests should be in writing and should be considered only if their nature falls within the uses and objectives stated by the registry. The recipient must also meet the requirements for safeguarding confidentiality. The communication of data should be done through secure means. Communication of data by telephone might not ensure a sufficient level of security. Also, electronic data should be protected by a high level of security.

The IARC is currently revising its confidentiality guidelines. We were told that the fundamental principles would remain essentially the same, and specific attention would be given to computerized data and other new technologies.

6.03 European Network of Cancer Registries (ENCR)

The European Network of Cancer Registries (ENCR) was established within the framework of the Europe Against Cancer Programme of the European Commission in 1989. The European Parliament adopted, on March 1996, an action plan to fight cancer.[130] This plan contains 22 measures, including provisions promoting the standardization and collection of comparable and compatible data on health as well as a clear intention to strengthen the European Network of Cancer Registries.

The objectives of the ENCR include improvement of the quality, comparability, availability and dissemination of cancer incidence data. The ENCR also facilitates cancer registration and collaboration between cancer registries by defining data collection standards and providing training for cancer registry personnel. The ENCR made a series of recommendations to its members regarding, for example, the description of the extent of the disease, multiple primaries and incidence date.[131] The ENCR is currently preparing guidelines on confidentiality in cancer registries.

The ENCR conducted an extensive survey of the basic characteristics of cancer registries in Europe.[132] The questionnaires touched upon all aspects of cancer registration from finances and confidentiality to data coding standards. More recently, another survey was conducted focusing on operational

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[130] EC, *Decision no 649/96/EC of the European Parliament and of the Council of 29 March 1996 adopting an action plan to combat cancer within the framework for action in the field of public health (1996 to 2000)*, [1996] O. J. L. 095/9.

[131] F. Berrino *et. al.*, "ENCR Recommendations: Extent of Disease" (1999), ENCR, online: <http://www.-dep.irc.fr/encr.htm> (date accessed: 29 March 2000); D. Pheby, *et al.*, "ENCR Recommendations: Multiple Primaries" (1995), ENCR, online: <http://www.-dep.irc.fr/encr.htm> (date accessed: 29 March 2000); D. Pheby, *et al.*, "ENCR Recommendations: Incidence Date" (1997), ENCR, online: <http://www.-dep.irc.fr/encr.htm> (date accessed: 29 March 2000).

[132] H. Storm, I. Clemmensen & R. Black, *Survey of Cancer Registries in the European Union*, IARC Technical Report No. 28 (Lyon: IARC, 1998).

aspects and areas of discrepancy between registries. A summary of the survey results was released in June 1999.[133] When asked about the source of information, 71% of the registries said they had direct access to pathology reports and 62% had direct access to medical and radiotherapy reports. A final report and analysis of the data is expected to be issued soon.

6.04 International Union Against Cancer (UICC)

The International Union Against Cancer (UICC) was founded in 1933.[134] It has more than 290 member organizations in 90 countries. The UICC is devoted to all aspects of the worldwide fight against cancer. It has developed 11 programs (divided into a series of projects), one of which is the CICA (Committee on International Collaborative Activities). This program is aimed at assisting countries in the formulation and implementation of national cancer control plans, including cancer registries. Another program called "Epidemiology and Prevention" also supports the creation of cancer registries.

A few Canadian organizations are among the members of the UICC, namely, the Fondation Québécoise du cancer, the Ontario Cancer Institute, Cancer Care Ontario, the National Cancer Institute of Canada and the Canadian Cancer Society.[135]

6.05 North American Association of Central Cancer Registries (NAACCR)

The North American Association of Central Cancer Registries (NAACCR) was established in 1987. The mission of the NAACCR is "to support and coordinate the development, enhancement and application of cancer registration techniques in population-based groups, so that quality data may be used for cancer control and epidemiologic research, public health programs, and patient care to reduce the burden of cancer in North America".[136] Members include cancer registries, governmental agencies, organizations, professional associations and individuals. All Canadian provincial cancer registries are members of the NAACCR. The organization is sponsored by Health Canada and Statistics Canada among others.

The NAACCR is committed to providing various standards to cancer registries in order to facilitate comparability of data. "Existing central registries in North America are a diverse group. Registries have been established at different times and for different purposes." The NAACCR supports this diversity of purpose and the resultant differences in configuration. Standards are different because registries have different purposes for being supported. However, when no standard exists, or a variety of standards exists for the same purpose, then NAACCR aims to recommend a single

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[133] L. Schouten, "Compact Results of the Follow-up Survey of Cancer Registries 1998" (Maastricht: European Network of Cancer Registries, 1999).

[134] International Union against Cancer (IUCC), Communications Department, "Introducing the UICC", online: <http://www3. uicc.org/publ/introducing.html > (date accessed: 13 March 2000).

[135] See the internet directory of the website of the UICC at <www.uicc.org>.

[136] NAACCR, "Mission, Goals, and Objectives 1996-2000", online: <http://www.naaccr.org/menu/objectiv.html> (date accessed: 29 December 1999).

standard.[137] NAACCR standards are not binding on their members.[138] Thus they are free to comply with them or not.

The NAACCR has established a set of standards for the collection, coding and exchange of data. The first series of guidelines relates to inter-state data exchange.[139] Since a population-based cancer registry must include all cancer incidence on its residents, it must establish some mechanism by which cancer diagnosed within its geographical boundaries are included in the registry but also outside its limits as well. Cancer data exchange is also useful to ensure completeness of the data. The NAACCR recommends that data exchange occur within a timeframe that allows the recipient to include the data in its final yearly report (no longer than 20 months). Since data quality is of great importance, the guidelines provides standards for outgoing and incoming data. Such standards include: running a virus check on the diskette, removing duplicate cases and using the NAACCR edit metafile to have a single record format and encrypt confidential data. Data may be exchanged through electronic data files, on paper or in computer reports. All exchanged data must be accompanied by the NAACCR data format used, the name of the contact person and an information sheet from the submitting registry. Both registries should enter into a formal agreement for data exchange, a sample of which is provided along with the guidelines. The agreement contains a full section on confidentiality which the registries undertake to keep the data confidential. Notification must be made to the source registry within 48 hours of any breach of confidentiality or if the data are released to a third party (e.g. under a legal requirement, a subpoena or for research purposes).

The NAACCR also provides mechanisms to improve and monitor the completeness and quality of data. Quite detailed and extensive standards are established in the *Standards for Cancer Registries Vol. III - Standards for Completeness, Quality Analysis and Management of Data*.[140] Section 1A of this document provides guidance for governmental authorities seeking to establish cancer legislation. According to the NAACCR, the creation of a central cancer registry by law is essential to cancer surveillance. Comprehensive legislation on cancer registries should touch upon the following topics: reporting requirements, patient record access, enforceability, data quality and standards, confidentiality and disclosure of data, liability and specific funding sources. "Cancer" should include all neoplasms as classified in the *International Classification of Disease for Oncology*.[141] According to these recommendations, the registry should be population-based and all cancers occurring in the geographic area covered by the registry should be reportable (including those of non-residents). Cancer should be reported to the cancer registry no later than 180 days after the time of admission or diagnosis. Legislation should enable access to medical records to obtain primary or complementary information. The confidential nature of the data should be reaffirmed, and the law should address when the data will be released, to whom and for what purpose. Access to confidential data should be granted provided the researchers comply with the confidentiality requirements and the research

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[137] Registry Operations Committee NAACCR, *Standards for Cancer Registries: Standards for Completeness, Quality, Analysis and Management of Data*, Vol. 3 (NAACCR, 1999).

[138] *Ibid.* at 1.

[139] J. Snodgrass, ed., *Procedure Guidelines for Cancer Registries: Series 1, Inter-States Data Exchange*, (Springfield, NAACCR, 1999).

[140] *Supra* note 139.

[141] World Health Organization, *International Classification of Diseases for Oncology*, 2nd ed. (Geneva : WHO, 1990).

project is approved by an Institutional Review Board (IRB). Aggregate data should be made available to the public. Cancer registry staff should be protected against liability for release of registry information in accordance with the law.

Further, these NAACCR standards also provide procedures for data security (s. IB8). All registry staff must be responsible for data security, but ultimate responsibility lies with the director of the registry. Staff should sign a confidentiality agreement. Suitable locks and alarm systems must be installed. Transmission of data should always be approved by the director and protected by precautionary measures. Computers containing the data must also be secured. Section 1C sets out the recommended time frame in which the report should be made. The NAACCR standards state that "[w]ithin 18 months of the close of a diagnosis year, the registry should contain at least 95% of the expected cases of reportable cancer occurring in residents during that year".[142] Section IIA provides basic quality standards. An overall quality assurance program should be implemented. Data management should also be carried out in accordance with NAACCR data standards (s. IVA).

Another important function of the NAACCR is to provide certification to registries that meet the minimum standards set by the organization.[143]

Finally, in 1999, the NAACCR issued a Policy Statement on confidentiality and security of data.[144] This statement describes the special nature of cancer registries with regard to general confidentiality rules. According to the NAACCR, for cancer surveillance to be fully efficient, cancer registries need to have access to all cancer diagnoses (without the possibility of opting out). The statement notes that this is already the case in a majority of states and provinces. In order to maintain public support and cooperation, cancer patients must be assured that confidentiality will be adequately protected and data will be used only for valuable cancer research projects and surveillance. Taking into account those considerations, NAACCR resolved that cancer registries must be maintained as a fundamental source to protect public health; that the public health surveillance system must be exempted from restrictions on the collection and retention of personal identifying data established in medical privacy legislation; that personal identifiers should be collected without consent; and that identifiable data within a registry must be protected against any disclosure in legal proceedings. This position adopted by the NAACCR certainly presents new matters for reflection in an area where privacy and confidentiality are at the forefront. The NAACCR is currently preparing detailed guidelines on confidentiality in cancer registries.

7.01 International examples of cancer registries

7.02 National Cancer Registries

From the United States to Estonia, cancer registries have multiplied around the world. However, the objective sought, the type of information contained in the records, and the way the registry is set up

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[142] This is compared with complete data retrieval within 20 months of the end of the year for SEER and within 6 months of the end of the year for the CDC. *Supra* note 142 at 44.

[143] According to the NAACCR Accomplishment Report (through April 1999), as of April 1999, 31 registries are certified.

[144] NAACCR, *Policy Statement 99-01: Confidentiality* (1999), online: <http:www.naaccr.org/menu/policy/confidentiality_policy_statement.html> (date accessed: 23 March 2000).

and managed vary from one country to another. Even within a given country cancer registries may not be homogenous because of the lack of national policy or government guidance.

In the next section, we will highlight specific provisions regulating national cancer registration. It should be said that we did not cover the whole legislative framework within each country (for example, we excluded from the analysis the complete coverage of all state or territorial policies). This section aims at providing an insight into what is happening in other countries with respect to cancer registration. We chose to describe the context in which national cancer surveillance is conducted in five countries, namely New Zealand, France, Germany, Australia and the United States. We focused our attention on central registries and nationwide policies.[145] We selected these five countries because of the relevant, comprehensive and interesting normative frameworks in place as well as the availability of literature in either French or English.[146]

7.02.1 NEW ZEALAND

The New Zealand National Cancer Register has been in operation since 1948.[147] It is a population-based tumor register of all primary malignant disease. In 1994, the *Cancer Registry Act*[148] came into force along with *Cancer Registry Regulations 1994*. The law provides that the Director General of Health is responsible for maintaining a national cancer registry. This legislation had a tremendous impact on the way cancer data are collected and stored in New Zealand. One of these fundamental changes concerns the reporting requirement. Since a significant number of cancers were unreported because the patient did not have to be hospitalized, the new legislation shifts the legal burden to report cancer diagnosis onto pathologists and the laboratories where the tests are carried out.[149] This method has proved to be effective. From 1993 to 1995, the National Cancer Registry saw an increase in the number of cases reported of 4.6%.[150] A fine of up to $500 may be imposed for failure to report a cancer as required by law or for a false report.[151] Along with the obligation to report cancer diagnoses, there is also a protection against lawsuits of the Act, for people who transmit information in accordance with the legislation (see Section 7). The detailed contents of the report are set by the regulation.[152] The report must be made no later than 21 days after the end of the calendar month in

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[145] Our research was limited to nationwide policies. States or provinces were generally excluded. However, since countries such as Australia and the United States have states or territories with the power to legislate with respect to health matters, we have included some examples of such legislation.

[146] We had to exclude interesting countries such as Finland or Japan because of the language barrier. We also had to exclude other countries because of the lack of a national policy.

[147] New Zealand Health Information Service, *Cancer: New registrations and Deaths 1995* (Wellington: Ministry of Health, 1999).

[148] *Cancer Registry Act*, No. 102 (1993), online: New Zealand Health Information Service <http://www.nzhis.govt.nz/cancer-act.html> (date accessed: 28 March 2000).

[149] *Ibid.*, s. 5.

[150] *Supra* note 149 at 8.

[151] *Supra* note 150, s. 8.

[152] *Cancer Registry Regulations 1994*, No. 89 (1994), online: New Zealand Health Information Service <http://www.nzhis.govt.nz/cancer-regs.html> (date accessed: 28 March 2000), at s. 4. It includes: name of the person who carried out the test and the physician, name of the patient, date of birth, sex, ethnicity, address,

which the cancer test was done. The regulation also provides that the report can be made either by written document, on a computer disk or by direct electronic communication.

The *Health Act 1956*[153] provides the general rules for control and notification of disease in the country. In 1993, the law was amended to include section 74 A, relating to the National Cervical Screening Register. Under this special provision, all cervical cancer smear test results are communicated to a register. The physician who requests the test must, before taking the sample, inform the woman of the existence of such a registration process. The woman may object to her inclusion in the registry or may request that all identifying information be removed. If no objection has been noted with the sample, the person in charge of the laboratory must forward the report to the National Cervical Screening Register. The registrars may not disclose nominative information unless the woman consents to it, the physician needs this information to assist in treatment or diagnosis, follow-up of the patient is required, a reminder to be tested must be sent to the woman or approved cancer research requires it.

The *Privacy Act 1993* provides the general rules governing the privacy issues in New Zealand. In accordance with the power granted by section 46 of the law, the Privacy Commissioner issued a code of practice related to health data, the *Health Information Privacy Code 1994* (hereinafter the "HIPC").[154] It provides the general rules of conduct for "health agencies" who handle nominative health information.[155] The national cancer registry, being set up by the Ministry of Health, is deemed to be a health agency within the meaning of the law. Researchers who are not health agencies are excluded from the privacy code, but the general rules of the *Privacy Act 1993* continue to apply.

The HIPC regulates data collection, use, storage and disclosure of health information. A health agency should not collect health information unless it does so for a lawful purpose connected with the function of the agency (rule 1). Generally, an agency may not use the information for other purposes (rule 10). As a general rule, health information must be collected directly from the person concerned (rule 2). There are exceptions to this rule, for example, if the person authorizes the communication or if it is used in research approved by an ethics committee, and will not be published in a form that could identify the individual concerned. With the approval of an ethics committee, the health agency may collect information directly from medical records, without the person's consent. However the ethics committee must be satisfied that complying with the general rules would prejudice the purpose of the data collection (rule 3 (4)(b)(ii)). Rule 5 requires the health agency to take reasonable steps to ensure data security and confidentiality. Rule 6 provides for a right of access of the individual to his or her data. Finally, rule 11 sets limits on disclosure of health information.

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occupation, category of cancer, anatomical site, qualification as primary or secondary site, description of the pathology, stage of cancer, etc.

[153] *Health Act 1956*, No. 065 (1956), online: New Zealand Government online <http://rangi.knowledge-basket.co.nz/gpacts/reprint/text/1956/an/065.html> (date accessed: 28 March 2000).

[154] *Health Information Privacy Code 1994*, Auckland (28 June 1994), online: Office of the Privacy Commissioner <http://www.privacy.org.nz/comply/hinfopc.html> (date accessed: 28 March 2000).

[155] The Ministry of Health is a "health agency" as designated by law (sch. 2 of the HIPC).

7.02.2 FRANCE

Cancer registration began in France in 1975.[156] Establishment of cancer registries was initially driven by local initiatives. To coordinate all these efforts and structures, INSERM (Institut national de la santé et de la recherche médicale), the main governmental body specializing in public health research, created the Comité national des registres in 1986.[157] Its mission is to propose a general policy on various registries (including cancer) based upon public health needs and to give advice to the government on the management, funding and creation of cancer registries. The Committee also provides certification to registries that meet a set of criteria.[158] Only certified registries are eligible for public funding. In 1997, 15 registries had obtained such certification.[159] Those registries are grouped in a network called FRANCI

Cancer is not a compulsory reportable disease in France. Registration is based on voluntary contributions and co-operation from various health professionals. In fact, in practice, it seems like practionners rarely notify cancer registry spontaneously. Alternative source of information are therefore considered. Cancer registries send "investigators" in public and private hospitals and clinics. They retreive information such as the name of the patient, residence, type of diagnosis, date of diagnosis and evolution. In France, the medical data from the death certificate is anonymous. Thus, it can not be used as a useful source of information. Direct computerized access to data from public health care insurance or from the registrar of civil status is also prohibited.

The protection of human rights and privacy issues are of great concern in France. Health care professionals are subject to severe rules on confidentiality. In fact, the general rules on professional secrecy are set out in the penal code.[160] It is considered a breach of confidentiality to communicate privileged information to a third party for purposes other than care (e.g. for research purposes) without the consent of the patient, and such a breach is punishable by penal sanction.[161] Further, the law of 1978 on computers, databases and liberty provides strict rules on the access, compilation and storage of personal data.[162] This law provides that every person has the right to object to his or her

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[156] L. Cherie-Challine, "La situation des registres en France en 1997" (1997) 17 Bulletin épidémiologique hebdomadaire, online: http://www.rnsp-sante.fr/beh/1997/9717/index.html.

[157] Arrêté du 10 fév. 1986, JO 13 mars, abrogé et remplacé par *Arrêté du 6 novembre 1995 relatif au Comité national des registres*, J.O., 11 novembre 1995.

[158] To obtain certification, a registry must obtain a favourable report from the Comité national des registres, a favourable report from the Comité consultatif sur le traitement de l'information en matière de recherche dans le domaine de la santé as well as an authorization from the CNIL (Comité national de l'informatique et des libertés). The certification is valid for 4 years, in the case of existing registries, and 3 years, for newly constituted registries.

[159] *Supra* note 158.

[160] *Nouveau Code pénal*, s. 226-13 &ff.

[161] *Ibid.*, s. 226-13.

[162] *Loi n° 78-17 du 6 janvier 1978 relative à l'informatique, aux fichiers et aux libertés*, J.O., 7 janvier 1978 [hereinafter *Loi n° 78-17*].

personal data being collected and stored.[163] The person whose data are requested must be informed of the addressee of the information as well as the right to access and correct the information collected.

In 1994, the *Loi no 94-548 du 1er juillet 1994 relative au traitement de données nominatives ayant pour fins la recherche dans le domaine de la santé*[164] provided new rules governing the use of health files for research purposes. These provisions safeguard fundamental rights while permitting cancer reporting. All "automated" data processing of nominative data for the purpose of research in health is subject to the provisions introduced in 1994. While the law enables the lawful communication of medical data by a health care professional (without breach of professional secrecy), it also tightens up the control and surveillance of the resulting databases. The law innovates by permitting the communication of confidential information by a health care professional when this communication has been approved by the Commission nationale de l'informatique et des libertés (CNIL) and the advisory committee.[165] This new legislation is supported by heavy penal sanctions for breach of confidentiality or failure to respect the procedure by which information should be collected, stored and treated. The first measure is the creation of an advisory committee on data processing in the field of health research. This organization must approve the research program before data collection begins on the basis of the research methodology and the relevance of requesting nominative data with respect to the scientific objective sought. A second authorization is required by the CNIL. The CNIL is concerned with data security and privacy of medical information. It is responsible for the proper treatment of nominative computerized data in accordance with the law.

Once authorisation is given, health care professional may transfer nominative health information to the designated cancer registry. Data must be transferred in a coded format unless justification is given.[166] Furthermore, resulting publication from research based on the data collected must never identify a given patient. This new legislation is supported by heavy penal sanctions for breach of confidentiality or failure to respect the procedure by which information should be collected, stored and treated. In fact, it submits any person who ultimately access the data for research purpose to the same duty of confidentiality than the health care professional. Breach of confidentiality is subject to the same penal code sanctions.[167] He also has an obligation to protect and adequately secure the data.[168] Finally, sanctions also apply when patient have not been individually notified that data may be transferred to a cancer registry by written documentation handed to the patient at his arrival to the health institution.[169] Exchange of data with an out-of-country registry will be authorized by the CNIL only if it is satisfied that the receiving state offers similar protection to the patients' personal

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[163] *Ibid.*, s. 26.

[164] J.O., 2 juillet 1994 [hereinafter *Loi n° 94-548*]. This amendment modified the *Loi n° 78-17*, *ibid.*, by adding chapter V bis.

[165] *Ibid.*, s. 40-3.

[166] *Ibid.*, s. 40-3.

[167] *Ibid.*

[168] *Loi n° 78-17*, *supra* note 164, s. 29.

[169] *Décret no 95-682 du 9 mai 1995* in application of the Chapter V bis of the *Loi no 78-17 du 6 janvier 1978*, s. 25-20 ff.

data.[170] Within the country there is a common database used for research. However, the information shared is strictly anonymous.

7.02.3 GERMANY

Germany is a pioneer in cancer registration.[171] At the end of the 1980s, there were extensive discussions within the scientific community regarding the problems that needed to be addressed in German cancer registration. The first observation was that registration was slowed down by very strict legislation protecting privacy (*Bundesdatenschutzgesetz*), which required, among other things, that person-related data be stored anonymously.[172] Germany is a federal State and data protection is under federal competence. The law permits an exception to this principle when the purpose of the research requires person-related data, and the identifying data are stored separately from the relevant data. Another issue was the lack of uniformity that characterized German cancer registries. Each "Laender" (or State) had different requirements for the reporting of cancer and different methods for compiling data. In this context, exchanging data and compiling them in a national survey was almost impossible. Following those discussions, in 1995 the *Gesetz uber Krebstregister* came into force. This new legislation on cancer registries was said to be "a compromise between the interests of data protection and epidemiologists."[173] The adoption of the legislation was in itself controversial as some groups considered that the Federal State was legislating in a "Land" field of competence. However, the Federal law had a limited lifetime. It expired last December and required that the "Land" develop their own legislation addressing particular aspects of cancer registration in a concerted way before its expiry date. It was aimed at guaranteeing a more complete recording of cancer in the German population as well as an adequate system of protection for medical and confidential data on a particular individual.

The legislation requires that each state set up a cancer registry within five years of the enactment of the law. States have the right to establish their own legislation provided that they maintain the minimum standards established by the federal legislation and do not modify the "double-unit" structure by which cancer data are collected and managed. Those registries should thus be compatible with one another. Once a year, all registries must send their epidemiological data to a central agency for national analysis (the Robert Koch Institute which belongs to the Federal Ministry of Health). Cancer reporting is not compulsory under federal law, but the States may elect to make it compulsory. The federal law simply gives the right to health professionals to report a cancer diagnosis without obtaining informed consent.

Among the important innovations proposed in the legislation is the creation of a scheme by which epidemiological information is gathered without breaching the legislation on privacy and confidentiality. Two entities are created, totally independent of one another, namely the confidentiality unit and the registry unit. The two units have different purposes. The confidentiality unit is responsible for gathering nominative information at the source. It receives the notification of cancer diagnosis

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[170] *Loi n° 94-548*, *supra* note 166, s. 40-49.

[171] Census and first types of cancer surveillance began in 1901. See D. M. Parkin, G. Wagner & C.S. Muir, eds., *The Role of the Registry in Cancer Control* (Lyon, France: IARC, 1985) at 5-6.

[172] N. Becker, "Cancer Epidemiology and Privacy Laws: Recent Trends in Germany" (1993) 29A(5) European Journal of Cancer 66 at 661-663.

[173] Bellach & D. Schön, "Legislation to Protect Individual Confidentiality: The Case of Cancer Registration in Germany" (1996) 184 (1-2) The Science of the Total Environment 33 at 33.

made by health professionals and on death certificates. This unit handles personal data including the name, address, age, type of cancer, date of diagnosis as well as epidemiological data such as birth place, gender, etc. The confidentiality unit checks the comprehensiveness, reliability and completeness of the data and may contact the physician for further explanations. The data are then encrypted and sent to the registry for storage and analysis. In fact, the confidentiality unit sends encoded identity data, epidemiological data as well as a control and identity number. Research can thus be conducted on anonymous data. After three months, all personal data are destroyed by the confidentiality unit. The registry unit's mission is to conduct research and analyze the data. Sometimes, permission may be sought to have access to certain types of personal information or to make some types of records linkage. To decrypt the identity data, the research unit must seek permission from the person holding the code (e.g. the person responsible for data protection) to conduct research at the level of the individual patient.[174]

7.02.4 AUSTRALIA

In Australia, health matters including cancer registries are, for the most part, regulated by the Territories or States. For example, the Australian Capital Territory has just enacted, under the *Public Health Act 1997*,[175] a regulation[176] that includes specific provisions for cancer registries. In this State, cancer is a notifiable disease. Cancer reports must be made by the pathologist who performed the test or the hospital (public or private), day procedures centre, outpatient department, radiation oncology department or nursing home where the patient resides.[177] The person in charge of the registry may request the physician to complete the report when necessary. The provider of information is protected against any lawsuit in relation to the communication of information and cannot be found in breach of confidence under professional standards of conduct. The Chief Health Officer in charge of the registry may disclose information contained therein to another Territory or State registry. He may also disclose information, upon the Minister's approval, to persons interested in cancer statistics or medical research, or any other person, provided the information is anonymous.

In comparison, New South Wales has provisions pertaining to cancer registry in the *Public Health Act 1991*.[178] According to section 16 of this Act, cancer is a notifiable disease in that State. Pathologists and any person who certifies the test results to the physician who requested it must make a report of cancer to the State registry. Failure to make the report in the prescribed form is an offence. A regulation[179] provides that the report must be made within 72 hours from the time the person who carried out the test has asked the medical practitioner concerned to provide the relevant information.

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[174] *Ibid.* at 35 and J. Michaelis & al., "A New Concept to Ensure Data Privacy and Data Security in Cancer Registries" (Proceedings of the Eight World Congress on Medical Informatics, Vancouver Trade & Convention Centre, 23-27 July 1995) at 662-663.

[175] *Public Health Act* (Australian Capital Territory), C.L. No. 69 (1997), online: AustLII Databases <www.austlii.edu.au> (date accessed: 29 March 2000, updated April 1998).

[176] *Public Health Regulations* (Australian Capital Territory), S.L. No. 1 (2000).

[177] As provided in the documents which accompany the Australian Capital Territory Cancer Notification Forms used as of April 1997.

[178] *Public Health Act* (New South Wales), No. 10 (1991), online: AustLII Databases <www.austlii.edu.au> (date accessed: 29 March 2000, updated 14 January 2000).

[179] *Public Health Regulation* (New South Wales), C.R. (1991), online: AustLII Databases <www.austlii.edu.au> (date accessed: 29 March 2000, updated 1 September 1999).

New South Wales has also set up a special Pap test register. The relevant provisions are in the *Public Health Act 1991*.[180] This register has a double objective: to monitor cervical cancer and to remind women to have a regular Pap test. An interesting point to note is that health care professionals are immune from liability by reason of notification, advice given to a woman based on the register or the failure to advise a woman based on the register. Nominative data may be given only to the woman in question, her physician, the pathologist who performed the test or any person designated by law, a court or the woman concerned. The report must be made within 30 days after the completion of the test, in a form approved by the Director-General, and must contain the information set out by law. Failure to make the report is punishable by law. Physicians have the obligation to inform women of the existence of the registry, its object and purpose. A woman may elect to have her identifying particulars withheld from the registry by notifying her doctor of her wish.

Finally, Northern Territory of Australia's *Cancer Registration Act* was enacted in 1988 and revised in 1997.[181] Pathologist and the Registrar of Birth Deaths and Marriages are entrusted with the duty to make cancer report to the registry. Pathologist have to report to cancer registrar any cancer within 7 days of the report confirming presence of the disease. Failure to make such a report may be penalized by a fine of $100. Moreover, unlawful disclosure of information collected for the purpose of the registry may is sanctioned by a $1000 fine. The registrar is in charge of the management of personal information. He may, at his discretion, publicize statistical data provided individual are unidentifiable. Registrar enjoys discretionary power related to the disclosure of specific information on a particular individual, provided that the Chief Health Officer, appointed under the Public Health Act, has authorized the release of information to undertake scientific research in accordance with the National Health and Medical Research Council guidelines. Written consent of the Registrar of Birth, Deaths and Marriages is however required to disclose any information he provided to the cancer registry.

Each regional cancer registry has particular agreements with the *National Cancer Statistics Clearing House* (NCSCH) to collect regional data. The NCSCH is responsible for the compilation of cancer data gathered through a network of State and Territorial registries, and dissemination of national cancer statistics. NCSCH is only a custodian of the information for the purpose of producing national cancer statistics. It is operated by the Australia Institute of Health and Welfare (AIHW).[182] The NCSCH Protocol[183] establishes the minimum data that a State must provide: full name, HASAC (Health and Allied Services Advisory Council) personal identifier, sex, date of birth, State/Territory registry case identification number, date of incidence, cancer site, histology, cause of death, date of death, geographic locator, country of birth and aboriginal status. Data must be transmitted on a tape or diskette. Having standardization in mind, NCSCH highly recommends the use of ABS, ICED codes and IARC rules for all registries. The protocol states in detail the security measures taken to ensure the confidentiality of the data.[184] All employees are subject to the confidentiality provisions set out

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[180] *Supra* note 180, s. 42 E &ff.

[181] *Cancer Registry Act 1988*, Northern Territory of Australia, as amended 1997.

[182] *Australian Institute of Health and Welfare Act*, No. 41 (1987).

[183] Australian Institute of Health and Welfare, National Cancer Statistics Clearing House (NCSCH) Protocol 2000 (unpublished) [hereinafter the "Protocol"].

[184] These measures include building security systems, restricted access to computers and sophisticated systems of accounts and passwords to gain access to the data (s. 5.1 of the Protocol).

in the *Australian Institute of Health and Welfare Act 1987*. Breach of confidentiality is a criminal offence.[185]

Australia has also developed quite an extensive normative framework dealing with privacy issues. The *Privacy Act 1988*[186] establishes the fundamental principles related to data protection, including special provisions related to the use of identifiable personal information in medical research. Its scope of application is limited to Commonwealth agencies (including the AIHW).[187] Part III of the Act, "Information Privacy Principles" (IPP) sets out the general rules for collection, storage, security, access, alteration, use and disclosure of health data. Along with the IPP, the National Health and Medical Research Council (NHMRC) has, in cooperation with the Australian Privacy Commissioner, issued guidelines for the protection of privacy specifically in medical research: *Aspects of Privacy in Medical Research*.[188] These guidelines give access to personal information for research purposes without all the requirements established by law, provided that an ethics committee approves the research and the proposed use (i.e. without specific consent of the individual). Disclosure of information by the NCSCH is thus subject to the IPP and NHMRC guidelines as well as all the conditions set out by each registry for its own data.[189]

7.02.5 UNITED STATES

Cancer surveillance in the United States is not organized in a single national system.[190] It is made up of the joint efforts of different regional systems of cancer registration. Cancer registration in the United States goes back to the 1920s.[191]

A number of governmental agencies and professional organizations bring different contributions to the battle against cancer. The National Cancer Institute (NCI) was created in 1937.[192] Its mission is to promote the coordination of research on cancer around the country. One of the important contributions of the NCI is the development of the Surveillance Epidemiology and End Results Program (SEER). This program oversees the collection and publication of cancer incidence from 11

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[185] *Crime Act 1914*.

[186] *Privacy Act* (Commonwealth of Australia), C.C.L. (1988), online: AustLII Databases <www.austlii.edu.au> (date accessed: 29 March 2000).

[187] Excludes States and local governments, as well as private agencies.

[188] National Health and Medical Research Council (Australia), *Aspects of Privacy in Medical Research* (Canberra : Commonwealth of Australia, 1995). A revised version has been issued : National Health and Medical Research Council (Australia), *Guidelines for the Protection of Privacy in the Conduct of Medical Research* (Canberra : Commonwealth of Australia, 1998).

[189] "Protocol," *supra* note 185, s. 5.2. The AIHW Undertaking which must be signed by the person to whom access to information is given. This undertaking is prepared in accordance with the principle of confidentiality set out in s. 29 of the *Australian Institute of Health and Welfare Act*, *supra* note 184.

[190] J. Swan & al., «Cancer Surveillance in the U.S.: Can We Have a National System» (1998) 83 Cancer 1282.

[191] In Connecticut. See the website of the National Cancer Registrars Association, "The History of Cancer Registries," online: < www.ncra-usa.org>.

[192] *National Cancer Institute Act*, P.L. 244, (1937).

population-based cancer registries spread around the country.[193] Another important government agency is the Centers for Disease Control and Prevention (CDC). The CDC manages the National Cancer Program introduced by the *Cancer Registry Amendment Act 1992.*[194] The purpose of the legislation is to implement State cancer registries or improve existing ones. It provides for federal funding when States invest their share of funding and create a legislative framework that addresses a list of specific issues designated by law.[195] The effect of the legislation is, in fact, to pave the way for national cancer surveillance through a system of contracts with each State. The National Cancer Registrars Association (NCRA) is a professional organization whose purpose is to establish standards of education for cancer registrars, disseminate information on the most recent cancer developments and make cancer patient data available for research.[196] An interesting contribution of the NCRA is the Registrars Code of Ethics (established 1986, revised 1995). The NCRA has also established an independent organization, the National Board for Certification of Registrars (NBCR), the purpose of which is to provide certification to registrars.

The American College of Surgeons founded the Commission on Cancer. The American Cancer Society is a voluntary association committed to cancer education and elimination. These three entities joined together to create the National Cancer Data Base.[197] This is a nationwide oncology outcomes database. The NCDB has been in operation for 10 years and it estimates that it retrieves 60% of all U.S. cancer cases. The database is administered in accordance with the standards set by the Commission on Cancer: *Standards of the Commission on Cancer, Vol. II: Registry Operations and Data Standards (ROADS).*[198] Data are reported to the NCDB without any identification of the patient.

Cancer registries are regulated by States. The methods used to establish cancer registries and the procedures adopted vary from one State to another. With the *Cancer Registry Act,*[199] the federal government created an incentive for States to enact legislation enabling the creation and maintenance of State cancer registries that address a common set of issues. Those issues include complete reporting of cancer by health facilities and health professionals, access to records for the purpose of completing the report, content and timeliness of the report, confidentiality of the registry, disclosure of data upon request, studies and analysis of the data and protection for individuals complying with the law.[200] The Act provided guidance and support for the creation of cancer registries around the

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[193] Surveillance Epidemiology and End Results, «About SEER» (National Cancer Institute), online : <http://www-seer.ims.nci.nih.gov/aboutseer.html> (last updated november 16th, 1999).

[194] *Cancer Registries Amendment Act*, Pub. L., No. 102-515, 106 Stat. 3372. The program was reauthorized by Congress in 1998.

[195] In a press release dated March 17, 2000, the NCI and the CDC announced a renewed collaboration. National Cancer Institute and National Institutes of Health, Press Release, "NCI and CDC Collaborate on a Comprehensive Cancer Surveillance and Control System" (17 March 2000).

[196] See the NCRA website at: <www.ncra-usa.org>.

[197] Online: <http://www.facs.org/about_college/acsdept/cancer_dept/programs/ncdb/ncdb.html>.

[198] Chicago: American College of Surgeons, 1996; Supplement 1998.

[199] *Supra* note 196.

[200] *Ibid.*, s. 2.

country and led the way towards a harmonized cancer surveillance system. In 1999, 45 States had authorizing legislation creating a statewide cancer registry, 39 of which comply with the specifications provided in the federal act.[201]

One example of a state-authorized cancer registry is the California cancer registry, established by the *California Health and Safety Code*.[202] Cancer, defined as all malignant neoplasms (including Hodgkin's disease and leukemia but excluding basal cell and squamous cell carcinoma of the skin), is a notifiable disease in California. Hospitals and facilities providing therapy to cancer patients have an obligation to report each new case. If the hospital fails to comply, the department of health may seek access to the information directly from the hospital or the facility and require the hospital to reimburse the State for the cost. A physician, surgeon, dentist, podiatrist or other health care practitioner diagnosing or providing treatment for cancer shall also report any cancer cases. Health care facilities and health care professionals are required to give access to their medical files for the purposes of gathering cancer data. Wilful failure to give such access may be punishable by a fine of $500 each day the access is refused. All the cancer data are confidential. However, they may be used for cancer surveillance or shared with other states, federal cancer control agencies, local health officers and researchers for research purposes. Out-of-state exchange must be subject to a written confidentiality agreement and the approval of an IRB. The *Health and Safety Code*[203] also has a section dedicated to the confidentiality of information collected by the registry for epidemiologic research. All the information collected for morbidity or mortality studies must be confidential insofar as the identity of the patient is concerned and must be used only for cancer research. The California Cancer Registry has also a policy of maintaining confidential any information that could identify the caseload of a specific facility or a physician.[204] The persons who submit cancer data to the health department, agencies or other cooperating individuals or agencies are not subject to lawsuits. The *California Code of Regulations*[205] implement the state statutes under title 17. Identification and collection of cancer data must be done by Certified Tumor Registrars. The time frame for the reporting of cancer is generally 30 days, except for "cancer reporting facilities," which have a delay of six months. Reports must be made according to the *California Cancer Reporting System Standards*.[206] Those standards are also used for defining the nature of the cancer to be included in the registry, organizing active follow-up of the pathology results and defining the reporting requirements (contents, format, codes, etc.).

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[201] Centers for Disease Control and Prevention, "Cancer Registries : The Foundation for Comprehensive Cancer Control : at a Glance (2000)," online : <http://www.cdc.gov/cancer/npcr/register.htm> (date accessed : 29 March 2000).

[202] California Health and Safety Code, § 103875-103885.

[203] *Ibid.*, § 100330.

[204] State of California Department of Health Services, *Cancer Reporting in California: Abstracting and Coding Procedures for Hospitals*, 5th ed., vol. 1 (California: California Cancer Registry Data Standards and Assessment Unit, 1998) at 3.

[205] *California Code of Regulations*, Public Health, Title 17, § 2593.

[206] *California Cancer Reporting System Standards*, vols. I, II, III, as updated from time to time.

7.03 Analysis of performance criteria in international cancer registry systems

This next section is intended to highlight some interesting and perhaps new initiatives in cancer surveillance taken around the world. Also, it aims to show current trends or issues related to cancer registration.

7.03.1 Sources of data

One of the great challenges that face registrars or those designing a cancer surveillance program is to ensure that they will be notified of all new cancer diagnoses within a given territory. Finding the appropriate source to cover the greatest number of cancer diagnoses is not an easy task. Sometimes, many sources must be targeted in order to get the full picture. The IARC acknowledges a few sources of cancer data[207]: the treating physician, surgeon, radiologist and radiotherapist; hospital admissions and records departments, the hospital discharge report; laboratories of pathology, cytology, hematology or biochemistry; medical records of social security systems; and coroners and vital statistics offices (death certificates). Since patients with cancer no longer necessarily need hospitalization, choosing only hospital records might not be a reliable way to get all the information required. Increasingly, laboratories play an important role in cancer surveillance as they are necessarily involved in any cancer diagnosis.

Reportable conditions vary according to the type of cancer registries put in place. An important international standard in this respect is the *International Classification of Diseases for Oncology* prepared by the World Health Organization.[208]

Where the law provides for the creation of a national cancer registry, it usually describes the contents of the report. Failure to make the report is punishable often by a fine. California, however, adopted an interesting approach. If the report is not made by the hospital or health facility (as required by law), the health department may search directly in the records and ask for reimbursement of the cost of this operation.

7.03.2 Management

(a) Administration

Countries have different strategies for cancer surveillance. Some have established a nationwide cancer registry (e.g. New Zealand). However, it is often the case that cancer surveillance is achieved by pooling regional resources together. This joint effort may be headed by a larger umbrella registry, or the data may simply be sent to a national centre for compilation of statistics (such as in Australia and England). Even within a state, the registration effort may be broken down into smaller regional registries, which will report their cancer cases to the State registry (e.g. California).

(b) Security

We seldom see direct reference to data security measures in the legislation. Security might be perceived as part of the internal structure of cancer registries. However, international agencies provide guidelines on this subject. The IARC devotes a whole section of its Confidentiality Guidelines to data security. The NAACCR also gives much attention to data security.

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[207] *Supra* note 130 at 5.

[208] *Supra* note 143.

(C) DATA QUALITY

The U.S. national program for cancer registries requires that States' registries comply with appropriate standards of completeness, timeliness and quality. Thus, California requires by law that a system of data quality control be maintained. However, as important as it may seem, data quality is not always mentioned in the legislation authorizing the creation of a cancer registry.

International guidelines place great emphasis on data quality. For example, section II of the Standards for cancer registries of the NAACCR is entirely devoted to data quality. Another important contribution on data quality is the report of the National Coordinating Council for Cancer Surveillance, *Team Building to Enhance Data Quality*.[209] The SEER program is also recognized as having a very solid data quality review.

(D) EXCHANGEABILITY AND COMPARABILITY OF CANCER DATA

At an international level, we observe a desire to ensure that data will be more easily compared or even exchanged. This may be necessary within a country where nationwide cancer surveillance rests on the sharing of data from different regional registries. International cancer surveillance also requires data comparability. In this context, different standards for cancer reporting and data storage are suggested by international organizations. In fact, cancer registries are sometimes subject to different types of standards for all aspects of registration.

Data exchange between registries within a given country is always permitted by law. Data exchange between out-of-state registries and other agencies is usually permitted under certain conditions. However, the requirements vary from one country to another. For example, in France, the recipient agency/registry needs to have comparable standards of confidentiality for data exchange to take place.

(E) REGISTRY PERSONNEL

Registrars and registry personnel are recognized as key players in a successful cancer surveillance program, as recently emphasized in the NCCS report.[210] Certification of registrars is awarded by some agencies (e.g. the NCRA). The NCRA also provides a code of ethics for cancer registrars. Furthermore, registry personnel are recognized as key players in any mechanism of data security. Increasingly, they are invited to enter into written confidentiality agreements and reminded of the duty of confidentiality. Finally, associations and agencies are offering training and education to registrars. Some type of certification is required by law in California.[211]

7.03.3 CONFIDENTIALITY, ACCESS AND USE OF DATA

The questions at the forefront of cancer registration these days are related to issues of privacy and confidentiality. With the rise of privacy protection, particularly in Europe, cancer registration along with any other type of epidemiological studies or morbidity surveillance have difficulty in finding a way to proceed without contravening the established legislation. There is a tension between the need to have a thorough review of all cancer incidence in a given territory and the need to respect increasingly severe rules of confidentiality. Often the rules on confidentiality provide that consent is required before data are gathered on a person. We even see opt-out provisions. Such a procedure is

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[209] H.L. Howe & G.G. Clutter, *Team Building to Enhance Data Quality*, (National Coordinating Council for Cancer Surveillance, 2000).

[210] *Ibid.*

[211] *California Code of Regulations*, *supra* note 207, Title 17.

not appropriate or compatible with cancer registration. For cancer surveillance to be efficient, it must be done on the population at large.

Recognizing that cancer surveillance is a legitimate concern that needs to be addressed, some countries have found ways to bypass even the toughest rules on confidentiality. One example of ingenuity is the German mechanism by which information is gathered and administered in two separate units. Another possibility is simply to exclude cancer surveillance from the legislation on privacy and confidentiality or to create a special set of rules that would respond to the needs of epidemiological studies and at the same time would protect the confidentiality of the data. The NAACCR Confidentiality Statement suggests that consent and the possibility to opt out should be excluded, provided that proper security and confidentiality mechanisms are put in place.

Major organizations are revisiting their confidentiality guidelines (e.g. IARC and NAACCR). We can therefore expect some interesting new avenues to be opened in the near future.

LIABILITY

Protection against liability is found in New Zealand, Australia and United States.

FUNDING

Insufficient information was available with respect to funding.

8.01 Confidentiality of health information: international comparative approaches

Although the concept of the confidentiality of personal medical data is well accepted by the general public and health professionals, the detailed practice is under potentially serious attack. Governments want access in order to combat fraud or serious crime or to improve efficiency of services; big business wishes to improve its competitive edge or reduce its costs by using detailed personal data in order to focus the promotion of its products and services; and health care organizations that do not keep their security measures up to the "state of the art" and are open to attacks on their personal medical data.[212]

A brief comparative overview of international (section A) and national (section B) developments on the confidentiality of health information over the last half century must cover both the right of privacy — medical confidentiality per se — and the protection of personal data. Together they overlap and sometimes co-mingle. Whether understood as a property or liberty interest,[213] private rights continue to expand the zone of personal intimacy free from public scrutiny. Medical confidentiality arises from both the nature of the information concerned and the fiduciary character of the physician/patient relationship. It has seen a movement towards greater patient involvement as opposed to professional control of health information. Finally, the recent appearance of personal data protection laws not only shields the individual from the powers of informatics but also provides a measure of security and personal control. Privacy, confidentiality and personal data protection are inseparable with regard to issues involving health information.

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[212] B. Barber, "Patient Data and Security: an Overview" (1998) 49 International Journal of Medical Informatics 19 at 25.

[213] S. Le Bris & B.M. Knoppers, "International and Comparative Concepts of Privacy" in M. Rothstein, ed., *Genetic Secrets*, (New Haven: Yale University Press, 1997) 418.

8.02 International standards and documents

In 1948, the United Nations adopted article 12 of the *Universal Declaration of Human Rights*[214] which upholds the protection against "arbitrary interference with [one's] privacy, family, home or correspondence" and "attacks upon [one's] honour and reputation". This same right is also found in the 1955 *European Convention on Human Rights*,[215] although the possibility of State "interference . . . for the protection of health" was specifically foreseen as a possible exception. The right to privacy was further strengthened by its inclusion in the 1976 United Nations *International Covenant on Civil and Political Rights*,[216] but it was both the Council of Europe's 1981 *Convention for the Protection of Individuals with Regard to the Automatic Processing of Data*,[217] which considered health data as "special," and the 1989 *Guidelines for the Protection of Privacy and Transborder Flows*[218] of the Organization for Economic Cooperation and Development (OECD) that established the modern parameters for the principled regulation and security of medical data. The eight OECD principles are 1) collection limitation; 2) data quality; 3) purpose specification; 4) use limitation; 5) security safeguards; 6) openness; 7) individual participation; and 8) accountability. The 1981 *Convention* in particular established exceptions for data banks for statistics or scientific research purposes as well as the rules for record linkage.

The last decade has also witnessed an increasing emphasis on patient autonomy and patient rights. Thus, according to the World Health Organization, all health status information should remain confidential even after death.[219] Concurrent with this expanding ambit of confidentiality is the notion of identifiability through personal data. The 1995 European Community Directive on the protection of individuals with regard to the processing of personal data and on

the free movement of such data[220] defines personal data as "any information relating to an individual or identifiable natural person (data subject)"; an identifiable person is one who can be "identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity."[221]

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[214] *Universal Declaration of Human Rights*, 10 December 1948, UN G.A. Res. 3/217A.

[215] *European Convention on Human Rights*, 4 November 1950, E.T.S. No. 5, 213 U.N.T.S. 222.

[216] *International Covenant on Civil and Political Rights*, 16 December 1966, Can. T.S. 1976 No. 47, 999 U.N.T.S. 171.

[217] *Convention for the Protection of Individuals with Regard to the Automatic Processing of Data*, 28 January 1991, E.T.S. No. 108.

[218] Organization for Economic Cooperation and Development, *Guidelines on the Protection of Privacy and Transborder Flows of Personal Data* (Paris: OECD, 1981).

[219] World Health Organization, *Declaration on the Promotion of Patient's Rights in Europe*, 1994, article 4.1.

[220] EC, *Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data*, [1995] O. J. L. 281/31.

[221] *Ibid.*, article 2.a.

However, it was the 1997 Council of Europe's *Convention on Human Rights and Biomedicine*[222] that included a new corollary right: "the right not to be informed about health information" within the concept of respect for private life and the right to information. In a sense, privacy in the health sector — once associated with property of medical records, then as a right of "secrecy" or otherwise specified as not to be personally identified or "processed" without consent — has now been extended to cover the sphere of personal intimacy through not being informed of one's own health data.

In that same year, the Council of Europe also adopted *Recommendation R97(5) on the Protection of Medical Data*.[223] Three articles bear mention here:

Article 1. An individual shall not be regarded as "identifiable" if identification requires an unreasonable amount of time and manpower.

Article 3.1. The respect of rights and fundamental freedoms, and in particular of the right to privacy, shall be guaranteed during the collection and processing of medical data.

Article 7.2. In particular, unless other appropriate safeguards are provided by domestic law, medical data may only be communicated to a person who is subject to the rules of confidentiality incumbent upon a health care professional, or to comparable rules of confidentiality, and who complies with the provisions of this recommendation.

The status of the Council of Europe's conventions is that of an international treaty and is binding on signatory states. The first article cited above again takes up the challenge of defining identifiability in a computerized society, thus adding the proviso "requiring an unreasonable amount of time and manpower." The second makes explicit the link between privacy and medical data (which, according to another article, includes genetic data). The third limits the persons who can receive such data to health professionals or those "with comparable rules of confidentiality." This latter requirement resonates with the "extra-territoriality" approach of the 1995 European Community *Directive* mentioned earlier, which is binding on countries within the European Union.

According to the *Directive*, not only must all 15 member states establish legislation that conforms with its standards but personal data cannot be transferred from an EU country to a non-EU recipient country unless the safeguards in the recipient country are deemed to afford "adequate levels of protection" (art. 25.1).

The processing of health data is not distinguished from that of other personal data, but the exemptions provided for under article 8 are certainly relevant:

> Where processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health care services, and where those data are processed by a health professional subject under national law or rules established by national competent bodies subject to the obligation of professional secrecy or by another person also subject to an equivalent obligation of secrecy.

Hence, the "EU regulation will permit cancer registration and linkages to other data files containing personal information without informed consent, as long as the processing is required for medical research and suitable safeguards are established, under the direction of a local supervisory

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[222] *Convention on Human Rights and Biomedicine*, 4 April 1997, E.T.S. No. 164.

[223] Council of Europe, *Recommendation No. R(97)5 of the Committee of Ministers to Member States on the Protection of Medical Data*, (1997), online: <http://www.coe.fr/cm/ta/rec/1997/97r5.html>.

authority."[224] Finally in 1999, the European Group on Ethics in Science and New Technologies issued an opinion on the *Ethical Issues of Healthcare in the Information Society*.[225]

Not only are the eight principles broader than the OECD data principles but participation and education have also been added to the traditional list.

The Group calls for a clear statement on rights and duties related to personal health data in the information society at a European level. Indeed, the opinion asserts the following:

1. A Directive on medical data protection is desirable within the framework of the current Data Protection Directive to address the particular issues arising from the use of health data.
2. A European patient's Charter covering the above aspects, possibly by means of a Recommendation, should be adopted.

In short, there are four well-established core information principles concerning personal data protection in Europe: a) statutory protection; b) transparent processing; c) special protection for sensitive data and, d) enforcement rights for individuals. Nevertheless, a recent study for the OECD on *Data Protection in Trans-border Flows of Health Research Data*, though supportive of self-regulatory codes of conduct (especially where there is scrutiny by a data protection authority and eligibility for funding), emphasizes the need for more consolidation.[226] Within the area of sensitive data, health information is increasingly being singled out as being in need of specific statutory protection, despite the application of the four core principles through a web of legal instruments. Nowhere is this trend more evident, however, than in national legislation.

8.03 National Privacy and Data Protection Laws

8.03.1 United Kingdom

In the United Kingdom, confidentiality is afforded both common law and statutory protection. Beginning with the common law, "[i]t is generally thought that the action of breach of confidence is now a *sui generis* action finding its roots in principle of equity, contract, property and tort."[227] The obligation of confidence arises both from the context in which information is communicated to the doctor and from the nature of the doctor–patient relationship. Furthermore, "important public interests favour ... confidentiality where personal information is communicated in circumstances in

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[224] H. Storm, I. Clemmensen & R. Black, *Survey of Cancer Registries in the European Union*, IARC Technical Report No. 28 (Lyon: IARC, 1998) at 29.

[225] European Group on Ethics in Science and New Technologies, *Ethical Issues of Healthcare on the Information Society*, Opinion No.13, 30 July 1999, online: <http://europa.eu.int/comm/secretariat_general/sgc/ethics/en/opinion13.pdf>. The principles are: 1) Privacy, 2) Confidentiality, 3) Principle of "legitimate purpose", 4) Consent, 5) Security, 6) Transparency, 7)Participation, and 8) Education.

[226] Organisation for Economic Cooperation and Development, *Data Protection in Transborder Flows of Health Research Data* (STI: Health Policy Brief) 1999 at 23. See also P. Schwartz, "European Data Protection Law and Medical Privacy" in M. Rothstein, ed., *supra* note 215, 392.

[227] I. Kennedy & A. Grubb, *Medical Law: Text with Materials* (London: Butterworths, 1994) at 497.

which it is clear that the recipient is expected to respect the privacy of that information."[228] In order to succeed in an action for breach of confidentiality, a plaintiff would have to show some form of injury (including mental distress) or economic loss.[229] Finally, contrary to civil law, a physician may disclose confidential information in the courtroom as a result of the public interest in the administration of justice, with the possibility that refusal could be considered contempt of court.

Common law may be modified by statute. For example, the *Data Protection Act 1998*[230] includes in its core principles the duty to fairly and lawfully process personal data. Sensitive data, whose definition includes health data, cannot be processed in the absence of explicit consent unless it is necessary for medical purposes or "is undertaken by ... a professional who in the circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person were a health professional" (Schedule 3, sec. 8).

It should be noted that the *Human Rights Act 1998*[231] incorporates the *European Convention on Human Rights*[232] in U.K. law. This guarantees the right to respect for privacy and family life. Superimposed on this, the *Data Protection Act 1998* just mentioned provides a framework of rights and principles governing the use of electronic or structured paper records (including fair processing). Nevertheless, in spite of the core principles found therein, the law does not specify when confidential information should and should not be disclosed to others, for research or most other activities. Thus, decisions must be made according to the common law on a case-by-case basis, even when a research project has been approved by a research ethics committee and authorized by a health authority.[233]

It also bears noting that in 1999, the British Medical Association (BMA) reiterated its request for statutory intervention to clarify the law with respect to the confidentiality of medical information in both the private and state sector.[234]

The general principles put forward by the BMA are as follows:

- Information disclosed should be the minimum necessary to achieve the objective and, whenever possible, anonymous.

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[228] *Ibid.* at 502.

[229] *Ibid.* at 514.

[230] *Data Protection Act 1998*, c. 29.

[231] *Human Rights Act 1998*, c. 42.

[232] *Supra* note 217.

[233] Medical Research Council, *Personal Information in Medical Research* (Guidelines), 1999, (s. 2.2.5).

[234] British Medical Association, *Confidentiality and Disclosure of Health Information*, Oct 14, 1999:
Confidentiality: The principle of keeping secure and secret from others, information given by or about an individual in the course of a professional relationship.
Disclosure: The revealing of identifiable health information to anyone other than the subject.
Personal health information: Any personal information relating to the physical or mental health of any person from which that person can be identified.
Anonymised information: Information which does not, directly or indirectly, identify the person to whom it relates.

- Patients should be made aware of the potential uses of their information, and be given an opportunity to object. Use of information for research is currently accepted as long as it is carried out within the guidelines and subject to monitoring by appropriately constituted research ethics committees. It is strongly recommended that patients be made aware that research is carried out, and that this may involve the use of their records unless they object.

Generally, the Association maintains that although research constitutes a justifiable use of personal health information, ideally it should use anonymous data wherever possible. The information disclosed should be the minimum necessary to achieve the objective. It may be possible to use pseudonyms or other tracking mechanisms for information that cannot be made anonymous, thus ensuring accuracy and minimizing the use of personal identifiers. Health professionals must make reasonable efforts to ensure that patients understand that their data may be used in research unless they exercise their right to object. Identifiable information should not be used for research purposes if the individual has registered an objection, nor should the contact names and details of potential participants in research be passed to researchers without consent.

Moreover, in these recent *Guidelines*, the BMA has taken the explicit position that "it is not ethically necessary to seek consent to the use of anonymous information." It also maintained the position that in addition to the traditional duty of medical secrecy "there is also strong public interest in maintaining confidentiality so that individuals will be encouraged to seek appropriate treatment and share information relevant to it." These recent Guidelines repeat the concern already addressed in the 1997 Caldicott Report[235] over the management and security of flows of information through new communication technologies. In short, the BMA maintains that the *Data Protection Act 1998* cannot adequately protect medical information.

Recently, the Medical Research Council maintained that

> [w]hen consent is impracticable, confidential information can be disclosed for medical research without consent if it is justified by the importance of the study; if there is no intention to contact individuals (except to seek consent) or reveal findings to them, if there are no practicable alternatives of equal effectiveness; and if the infringement of confidentiality is kept to a minimum. (Key Principle B)[236]

With regard to this Principle, the document notes that the "decision about whether a study is sufficiently important is not for the investigator alone, but must also be referred to a Local Research Ethics Committee for independent assessment." The techniques required for the use of personal health information in research are encoding or making the data anonymous "so far as is reasonably possible." The latter are understood to be the equivalent of unidentifiable data, meaning that all information that could directly identify the individuals involved has been irreversibly removed.

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[235] United Kingdom, *Report on the Review of Patient-Identifiable Information* (Department of Health, 1997) (Chair: Dame Fiona Caldicott).

[236] *Supra* note 235.

A recent case heard by the Court of Appeal (December 21,1999)[237] reversed a High Court ruling[238] that the collection and sale of data on doctors' prescribing habits breached confidentiality, even when the data were anonymous. The case hinged on the issue of implied consent to the use of anonymous data "not only by commercial companies but for public interest purposes, including medical research and statistics."[239]

The Court of Appeal held that for breach of confidence to occur the information must have the necessary quality of confidence about it; be imparted in circumstances that bestow an obligation of confidence; and be an unauthorized use of that information to the detriment of the party communicating it". The Court of Appeal held that because the data were anonymous "[t]he patient's privacy will have been safeguarded, not invaded. The pharmacist's duty of confidence will not have been breached". It is interesting to note that albeit *in obiter*, the Court of Appeal suggested that such anonymous data would also not run afoul of articles 2(b) and 8 of the European *Directive* of 1995.

8.03.2 AUSTRALIA

"The law relating to privacy in Australia is unsatisfactory. There is no general common law or statutory right to privacy. Such general privacy laws which do exist have developed in a piecemeal fashion."[240]

In Australia, as in the United Kingdom, medical practitioners have no professional privilege.[241] Furthermore, any breach of confidence by a general practitioner may lead to disciplinary action or to civil actions rising out of tort, contract or equity. There are also statutory provisions and guidelines imposing the requirements of confidentiality, including circumstances that constitute exceptions to confidentiality. An interesting position is that medical records are the property of the private medical practitioner, who can allow or deny access (except for the Australian Capital Territory).[242] The same does not hold for public health facilities.

The Commonwealth *Privacy Act 1988* applies to research on personal information held by a Commonwealth agency.[243] It establishes the fundamental principles related to data protection, including special provisions related to the use of identifiable personal information in medical research. The Guidelines for the Protection of Privacy in the Conduct of Medical Research of the National Health and Medical Research Council (1998) not only require that each research project be approved by an Institutional Ethics Committee but also that

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[237] *Re Source Informatics Ltd.*, (21 December 1999) Case No. QBCOF 1999/0639/C, online: <http://wood.ccta.gov.uk/courtser/judgements.nsf>.

[238] *R* v. *Department of Health, Ex Parte Source Informatics*, [1999] All E R 185.

[239] C. Dyer, "BMA's Patient Confidentiality Rules are Deemed Unlawful" (1999) 319 BMJ 1221.

[240] D. Chalmers, "Australia" in H. Nys, ed., *International Encyclopedia of Laws: Medical Law*, vol. 1 (Boston: Kluwer Law International, 1998) 1 at 79.

[241] *Ibid.* at 77: "...in Victoria, Tasmania and the Northern Territory there is a privilege contained in the relevant state legislation which allows a doctor to refuse to divulge confidential information in Court proceedings unless the patient consents to the disclosure."

[242] *Breen* v. *Williams* (1996) 70 ALJR 772.

[243] States and local government, as well as private agencies, are therefore excluded.

2.3 The written protocol for the conduct of each medical research project should state:
a) the reasons why personal rather than de-identified information is needed;
b) why consent to the use of personal information cannot be obtained from the individuals involved;
c) the safeguards that will be applied to protect personal information that will be made available to other researchers or third parties;

Furthermore, the Institutional Ethics Committee must weigh the public interest in medical research against the public interest in privacy (art. 3.2). If public interest in research substantially outweighs its interest in privacy, then the research will not be considered a breach of the *Privacy Act*.

8.03.3 FRANCE

Article 9 of the French *Civil Code* proclaims the right to privacy. Protection of health information, however, stems chiefly from the *Penal Code* (art. 226-13 and 14). This means that the sanction for breach is a criminal one, the information transmitted by the patient is of a highly personal nature (*intuitu personnae*). Furthermore, whereas most obligations of a physician are what are known as an obligation of means, medical secrecy is one of the results. This is important, since the ambit of the medical secret extends beyond what is heard, observed or confided to what is understood. Thus, simple proof of breach is sufficient to constitute a fault.[244] According to the 1978 *Law on Computers, Records and Freedoms*[245] every person has the right to object to the collection and storage of personal data and to access to such data.

In a major statutory amendment in 1994 to the French omnibus data protection law,[246] French legislators set out restrictions on the automatic treatment of personal information for the purpose of health care research. This statute sets up a new body of data protection oversight, establishes substantive principles for data protection in medical research, and specifies important individual interests that must be respected before personal information can be used in a health care research project. Each request to process information for medical research is to be submitted first to the Consultative Committee on the treatment of information for purposes of research in the health care sector of experts, who are then to notify the National Commission on Information and Liberties (CNIL).[247]

In 1995, the revised *Code of Ethics* for physicians, the number of articles addressing medical secrecy with reference to the additional conditions established by law for the protection of personal information was increased. Disciplinary sanctions are independent of any civil or penal ones. Finally, specific laws govern not only the computerization of medical data but also the gradual introduction of the smart card in the health-care system.

In addition to setting up a new body of oversight, the 1994 amendment also establishes important individual interests. Most important is a general requirement for personal medical information that permits the identification of individuals to be encoded before transmission to a research project. Although there are exceptions, the law forbids the reporting of research results that permit the direct or indirect identification of concerned parties. The law also grants the individual a right to object to

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[244] See generally, M. Gérard, "France" in H. Nys, ed., *supra* note 242, 1 at 138-146.

[245] *Loi n° 78-17*, *supra* note 164.

[246] *Loi n° 94-548*, *supra* note 166.

[247] Schwartz, *supra* note 228 at 403-404.

use of their data in any medical research project. Finally, treatment of one's health care information in a research project generally requires the individual to be personally informed of the nature of the transmitted data, have the right to access the information and to correct the information; and be aware of the intended recipient and the end use (finalité) of the information.[248]

In France, the Consultative Committee on the treatment of information in research and health care is empowered by the CNIL to receive requests from researchers to use nominative information without consent: first, if notification of the change of recipient of nominative information would be impracticable; second, if the information is unknown to the person; and third, if the information concerns a required notifiable condition. The only restriction is that the data be coded.[249]

In 1997, the CNIL adopted a recommendation on the treatment of personal health data.[250] This recommendation reiterates the obligation to maintain confidentiality, to inform the person of any transmission of information with the possibility of objection, and finally, requires that data be made anonymous for any secondary uses. Where information systems involve ongoing follow-up and updating, it is recommended that the information undergo coding, encryption or scrambling. In addition, by having adopted heightened security measures for medical data, the Commission can at any time verify that these conditions have been respected. Yet, the Commission affirmed that in conformity with article 5 of the 1981 *Convention on the Automatic Processing of Data*, access to nominative medical data for proper follow-up, inclusion of such data for the purposes of state social security programs, for prevention strategies or for statistics or research was not precluded provided the data are encoded or made anonymous.

8.03.4 ICELAND

On December 17, 1998, the Icelandic Parliament adopted an *Act on a Health Sector Database*.[251] This Act foresees the creation and operation of a centralized database containing non-personally identifiable clinical data. Companies can apply for a licence in order to have access.

Article 7 of the Act states that with the consent of health institutions or self-employed health care workers, data derived from medical records may be delivered to the holder of the operating licence (the licensee) for transfer into the health sector database. The same Article provides that the process will be subject to the conditions regarded as necessary by the Data Protection Commission at any time, and that personal identifiers shall be encrypted before transfer to the database, so that the employees of the licensee work only with non-personally identifiable data. Personal identifiers will be encrypted by one-way encryption that does not allow them to be traced back by using a cipher. The Data Protection Commission will carry out further encryption of personal identifiers using the methods that the Commission deems will best ensure confidentiality.

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[248] *Ibid.* at 404.

[249] *Décret n° 95-682 du 9 mai 1995*, J.O., 11 mai 1995, art. 40-3, al. 2.

[250] National Commission on Information and Freedoms (CNIL), *Traitement des données de santé à caractère personnel*, Recommendation No. 97-008, 4 February 1997, *Journal Officiel* 12 April 1997, online: <http://www.cnil.fr/uk/index.htm>.

[251] *Act on a Health Sector Database*, Act no. 139/1998, Iceland, 1998-1999, online: <http://brunnur.stjr.is/interpro/htr/htr.nsf/pages/gagngr-log-ensk>.

It is important here to underline the fact that it is the employees of the health institutions in question or self-employed health workers who prepare the data for transfer to the database and not the employees of the licensee.

Article 10 of the Act states that the licensee is permitted to process the clinical data in the health sector database derived from medical records provided that the data are processed and connected in such a way that they cannot be linked to identifiable individuals. The Article provides, furthermore, that the licensee will develop methods and protocols that meet the requirements of the Data Protection Commission in order to ensure confidentiality in connecting data from the health sector database with data from a genealogical database and a genetic database.

The Article furthermore provides that the licensee is not permitted to provide information on individuals and that this should be ensured, e.g., by limitation of access.

The Act contains detailed provisions on monitoring, which is entrusted to three parties: the Operating Committee, which will monitor the creation and operation of the database, the Data Protection Commission, which is subject to the Ministry of Justice and is responsible for general surveillance of personal privacy in Iceland, and an Interdisciplinary Ethics Committee, which monitors queries and research conducted using data from the health sector database.

Finally, it is interesting to note that according to Article 1.8, all data entering the health sector database are the common property of the Icelandic nation and in the care and under the responsibility of the Minister for Health and Social Security, acting for the Icelandic Government. This applies both during the time that the operating licence is in effect and after its expiration.

There has been much discussion as to whether this law is in conformity not only with domestic law (*A Special Act on the Rights of Patients*;[252] *Reg. No. 227/1991 on Medical Records and Compilation of Reports in Health Matters* pursuant to the *Act on Physicians* and the *Act on Health Service*) but also with European standards of data protection and with scientific freedom generally.[253]

On January 22, 1999, the Ministry of Health and Social Security made preparations to issue an Operating License for the Creation and Operation of a Health Sector Database of non-identifiable health information. The licensee is authorized to convert information in the health sector database for linkage with a genetic database with the approval of the Data Protection Commission.

No genetic information or samples can be obtained for research purposes without specific patient consent. It goes without saying, however, that any such information found in the medical record would automatically be in the health sector database unless the patient has exercised the opting-out provision.

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[252] Act no. 74/1997.

[253] For a favourable view of the law, see O.M. Arnardóttir, *et al.*, "The Icelandic Health Sector Database" (1999) 6 European Journal of Health Law 307. For a contrary position, see H. Roscam Abbing, "Central Health Database in Iceland and Patient's Rights" (1999) 6 European Journal of Health Law 363.

8.04 Conclusion

Considering the often eclectic if not confusing state of the law as a result of the combined effect of privacy, medical confidentiality and personal data protection, it is difficult to draw any conclusions except perhaps to argue for the consolidation and harmonization of health data protection policies and legislation. This is because although the trends in all three sectors are welcome, their combined effect creates uncertainty, since it is not always clear which rules apply. Moreover, most countries also provide for recourse to overarching constitutional protection or, in the absence of such, to human rights legislation, be it national or regional, as in Europe. Such consolidation and clarification, including the ambit of legitimate exceptions, would not only be welcome but perhaps serve as first step towards an international "Charter" on health information.

Consolidation and harmonization of health data protection policies and legislation is needed.

Furthermore, we are now witnessing a further expansion of health information protection and promotion in the emergence of the right not to know and in the area of research, in the move from coding or encryption of information to making it anonymous. Both of these recent developments are not without implications, for example that the individual has been effectively removed from ongoing communication of health information issues. Four questions remain: What degree of informed consent is required for the valid exercise of the "right not to know". Will making the data anonymous, though legally and ethically expedient, ultimately harm good science? In the long run, will both of the above statements impede identification for follow-up for proper medical treatment? If so, have we unwittingly created a system of overprotection of the individual to the detriment of population health through prevention?

Moreover, in this search for guidance and clarity, health information should be distinguished from the sometimes draconian overreach of personal data protection, often aimed at thwarting access by commercial bodies. The indiscriminate application of this legislation when combined with the moral or legal force of medical codes of ethics can indirectly harm individual health to say nothing of blocking the State's legitimate role in health systems planning. The majority of countries studied here cannot properly fulfil this latter obligation. In the rush to promote individual privacy and autonomy with regard to health information, we may have lost sight of the larger picture of the health of society and that of future generations.

9.01 Issues and recommendations

Although it was not the purpose of this project to produce detailed recommendations for legal reform or other action, we have summarized below some of the issues that we have identified as requiring particular attention or further consideration. In the first section, we review some of the most important issues that were revealed by our assessment of Canadian legislation according to the performance criteria. The sections that follow deal with a range of issues relating to coordination and harmonization, expansion and integration of surveillance activities, informed consent and transparency, identifying and non-identifying information, management and personnel of cancer registries and, finally, oversight and accountability.

9.02 Performance criteria

As previously noted, we found significant gaps and inconsistencies when comparing legislation in the various Canadian jurisdictions with each other and with the performance criteria. There are issues to be resolved with respect to each of the criteria. Some areas that particularly need to be addressed are:

- Reporting requirements: there are significant differences as to what events or conditions are reportable and what information must be reported, which presumably have a negative impact on comparability of data.
- Relatively few jurisdictions have mandatory requirements. The existence of a mandatory requirement may not necessarily be essential if there are other ways to ensure completeness, but if it is considered essential or desirable, the requirements should be created.
- Mandatory reporting requirements are not always supported by provisions setting out offences and penalties. In the absence of such provisions, there is no way to enforce mandatory requirements.
- Reporting requirements may be contained in stand-alone cancer legislation or as part of a more general statute (or regulation under a general statute). The latter approach may allow for more flexibility in expanding and integrating surveillance activities.
- In many cases it is quite difficult to identify all of the legislation applying to collection of data from other sources. Further clarification and integration of these provisions would provide greater certainty and transparency.
- Similar concerns apply with respect to the rules regarding confidentiality and access to data for research.
- The penalties for misuse of data or illegal access to data should be re-examined. Prohibitions must be backed up by offence and penalty provisions. Where there is an agreement regarding access to and confidentiality of data, breach of the agreement could result in penal sanctions as well as termination of the agreement.
- Not all jurisdictions provide protection against liability for reporting. It is only logical to provide such protection if reporting is mandatory or if we want to encourage reporting. However, there is no clear justification for restricting this protection to cancer reporting; it should apply to any communication of information for morbidity registration, pursuant to a statute and to an approved registry.
- Provisions on security and data quality were not found in the Canadian cancer statutes. (Security requirements may in some cases be dealt with in privacy legislation.)
- Statutes should contain provisions regarding acceptable uses and disclosures of registry information. Internal use, as well as disclosure, should be restricted to certain acceptable purposes. Information on these purposes should be available to the public to comply with the principles of transparency and purpose specification.

9.03 Coordination of health policy and legislation

The review of Canadian statutes relevant to cancer surveillance revealed that a large number and variety of pieces of legislation may affect cancer surveillance practices. Many other pieces of legislation or policies within the health system, and even beyond, may also indirectly affect the availability of information. For example, changes in payment systems may affect insurance information, which is likely to be used as a source for cancer registries. This interdependence, which will only become more important as registries seek to expand their scope, highlights the need to raise awareness and engage in continued dialogue within the health sector so that impacts on registration activities can be identified and considered at an early stage.

When comparing legislation in the various Canadian jurisdictions, significant gaps and inconsistencies were found.

The development of privacy and data protection legislation is the area that most affects surveillance activities, and failure to address surveillance needs in the drafting of such legislation can lead to serious problems. Epidemiological research sometimes does not seem to have been considered in drafting legislation. In some countries, legislation on privacy, data transfer, and medical law have made population health research difficult or even impossible. The goals of such legislation are clearly legitimate, but so too are the goals of cancer surveillance and other public health activities. The federal government has an obligation to ensure better health for all Canadians. A balance must be

struck between protection of privacy and protection of health, and approaches developed that maximize protection of both.

For all existing or proposed legislation, the impact on and any conflicts with surveillance must be identified. In the event of conflicts, consideration must be given to (a) whether surveillance practices can and should change to comply with important principles and standards, and (b) if not, how the legislative framework should be modified to allow these activities to proceed. There are several different ways of accomplishing this. Exceptions can be written into the main legislation or regulations, some or all of the provisions of cancer-specific legislation can expressly take precedence, or cancer activities can be excluded altogether from the scope of legislation.

For all existing or proposed legislation, the impact on and any conflicts with surveillance must be identified.

If cancer surveillance is to be excluded from or given special treatment under privacy legislation, one must then ask whether there is anything specific about cancer that justifies treating it differently from other types of public health surveillance. We need to look at public health surveillance as a whole and encourage public debate in this area generally to determine which diseases should benefit from any exception or special treatment. Cancer surveillance is distinct from surveillance of communicable diseases, and justifiable differences in the legislative treatment of these exist. However, it is questionable to what extent cancer can be usefully distinguished from other important non-communicable diseases (e.g. heart disease). Furthermore, as the Canadian health surveillance system moves towards increasing integration, the legislative framework must facilitate this goal if it is to be accomplished effectively.

9.04 Legal reform and harmonization

As noted above, there is a great degree of variation among Canadian jurisdictions with respect to the legislative framework for cancer surveillance. This surely must affect the ability to exchange and compare data, and will be a barrier to further integration. In addition, the legislative framework in most jurisdictions fell far short of the performance criteria suggested by the Canadian Coalition on Cancer Surveillance. Although the actual *practice* of cancer surveillance in Canada may be more consistent than this review of legislation would suggest, the fact remains that there are significant gaps and inconsistencies in the legislative framework.

This is a matter that clearly requires attention. It also raises the question as to what is the best way to promote harmonization – whether it be through legislative reform, adoption of uniform codes and practices, certification schemes, other mechanisms or some combination of these. Which matters must be dealt with in legislation and which can be left to regulations, codes of practice and other documents should be considered carefully.

Harmonization of privacy legislation and data collection standards must be a priority.

Harmonization is also essential in the international context. There are two key areas where harmonization is most needed: privacy legislation and data collection standards. Canada should not isolate itself but, rather, should take account of international standards and examples in any initiatives. One example of the importance of such harmonization is the effect of the EU Directive, which requires that any country to which data will be transferred have an equivalent level of protection. If Canada does not meet this level, it may be excluded from data exchange. Consistent standards for identification of cases, collection, data quality, data transfer, etc. are also essential. Again, some of

this is best dealt with in legislation while other aspects may be left to codes, standards and agreements.

Finally, any efforts with respect to legislative reform should consider how to achieve reform with a minimum of disruption. Changes to legislation affect the availability of data and may impair comparability of data. Some disruption may be inevitable, but perhaps it can be minimized if attention is paid to this issue.

9.05 Expansion and integration of surveillance activities

Current plans to expand and integrate surveillance activities raise a number of legal issues and challenges for legal reform. As increasing automation allows easier linking of cancer data with other health information and other kinds of personal information, we need to address issues similar to those already identified regarding privacy protection, comparability of data, data quality, and etc. in a broader context. The potential for legal challenges may increase as systems become more extensive and integrated, and people perceive a greater threat to privacy. Data linking and the use of common identifiers are often considered threats to privacy.

As registries expand and integrate, it will be increasingly important to address unresolved issues regarding access to registry information. Access may be sought for treatment and follow-up, and within the area(s) of research — cancer-related, health or other research. It must be decided which of these purposes will be permitted, and this should be clearly reflected in the legislation. The individual's right of access to his or her own information will also need to be clearly addressed in the registry context.

We will also need to examine the way tissue banking and advances in genetics may change – even revolutionize – cancer surveillance. The existing legislation does not address these issues.

9.06 Informed consent and transparency

As a general rule, obtaining the subject's consent is the way that one legitimizes what would otherwise be a breach of confidentiality and the right to privacy. In surveillance and some health research, however, a consent requirement is problematic because it precludes comprehensive coverage.[256] These considerations may justify collection, use and disclosure of information without informed consent, although only to the extent that it is truly necessary. The justification for dispensing with consent may not extend beyond basic surveillance activities and research; further discussion and public debate of the exact scope of this justification is required.

However, we also need to consider the principle of transparency, which is a related but distinct principle from informed consent. Transparency requires that individuals and the public at large be aware of surveillance activities and the information practices of cancer agencies. This principle of transparency should be adhered to even when consent is not required. Public education on the activities of cancer registries and the benefits of cancer registration should also help to establish support for these activities.

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[256] M.P. Coleman, C.S. Muir & F. Ménégoz, "Confidentiality in the Cancer Registry" (1992) 66 Br. J. Cancer 1138 at 1139; P. Starr, "Health and the Right to Privacy" (1999) 25 Am. J. L. & Med. 193 at 199.

9.07 Identifying and non-identifying information

Cancer registration, in order to be effective, relies on the collection of individual identifying information.[257] Effective surveillance needs to be more than merely a registry of cancer deaths – this information is already available from vital statistics registries. Information from various sources must be collected and integrated. Cancer surveillance must be part of a "living" system that can take into account the context of the development of the disease. Some kinds of research using cancer information may also require identifying information for similar reasons. This need for identifying information sets cancer surveillance apart from some other uses of health information that are commonly discussed in the context of health privacy.

The prevailing attitude reflected in privacy legislation and guidelines is that the collection, use and disclosure of individual identifying information should be restricted as far as possible. The need for this information in cancer surveillance and research needs to be clearly supported and articulated, so that privacy advocates and legislators are aware of the justifications. Especially with respect to use in research, alternative approaches such as coding should be further explored. The German cancer registry is an interesting example of one possible approach.

Where non-identifying or aggregate information is sufficient, further thought must be given to the need for some restrictions on use or disclosure. The current legislative framework seems to assume that any use or disclosure of non-identifying information is innocuous, but this may not always be the case. Disclosure of information that can be tied to identifiable groups rather than individuals may, for example, lead to discrimination or other harms. Public disclosure of a high incidence of cancer (or a particular cancer) in an identifiable group might not be considered a breach of "privacy" but may nevertheless lead to some of the same harms. This is an area in which epidemiology, which deals with population-based research, can be at the forefront of identifying and implementing ethical practices to take into account these types of interests.

9.08 Cancer registries management and personnel

Issues relating to transparency and public accountability have important implications for the management of cancer registries. It should be clarified to whom the management is accountable. The principle of transparency would suggest that internal policies should be public and easily accessible. Cooperation with privacy commissioners is recommended (see below), as is the establishment of an internal officer responsible for privacy issues and concerns.

The registrars of cancer registries are key players in cancer surveillance and should be recognized as such. Since they are entrusted with highly sensitive information, perhaps there should be some mechanism for certification or approval as there is in some jurisdictions. Certification and training requirements should be addressed in legislation.

9.09 Oversight and accountability

Adequate oversight and structures of accountability can work within any given legislative structure to prevent or identify abuse or misuse of information, and thus instill confidence in members of the public that their personal information is being used responsibly. There are a number of different mechanisms that may be used. Criminal penalties should be reserved for the most egregious abuses. Fines and other non-criminal punitive measures can be used to deter and punish other misuses of personal information, and are also commonly used to compel reporting of cancer cases.

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[257] See Coleman, Muir & Ménégoz, *ibid.* at 1138-39.

Many researchers and individuals providing information to registries are already bound by professional codes of ethics, for example for physicians. Some efforts have also been made to develop codes of conduct specifically for epidemiologists or cancer registrars; this possibility should be explored. In addition, relevant professional codes should be examined to ensure that they do not prevent or undermine effective surveillance activities but otherwise provide sufficient protection for personal health information.

Research ethics boards play an important role in supervising and approving research. Under new Canadian health information statutes, they play an important "gatekeeper" function in providing approval before individual identifying information may be released.

Finally, in many jurisdictions FOIPP legislation and/or health information legislation has established a position entitled Information and Privacy Commissioner who is responsible for overseeing information practices subject to the legislation. These commissioners typically have very broad mandates and can serve as useful resources on privacy issues. The cooperative relationship between the B.C. Cancer Agency and the B.C. Information and Privacy Commissioner, as shown by the recent audits, recommendations and consultations,[258] should be looked to as a model of how cancer agencies can benefit from the oversight of such bodies. Cancer agencies should be encouraged to make use of these resources and to view the relationship between their work and the privacy commissioners' work as complementary rather than antagonistic. Consultation with privacy commissioners should also be considered as a useful part of any legislative reforms.

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[258] See D.H. Flaherty, "The British Columbia Cancer Agency: The Results of a Privacy Check-Up" (Victoria, B.C.: Information and Privacy Commissioner of British Columbia, 1997), online: http://www.oipbc.org/investigations/site_visits/Cancer.html; D.H. Flaherty, "Two Years Later: Results of a Privacy Check-Up of the British Columbia Cancer Agency" (Victoria, B.C.: Information and Privacy Commissioner of British Columbia, 1999), online: http://www.oipbc.org/investigations/site_visits/Cancer2.html.

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Table of Canadian Legislation

	CANCER	PUBLIC HEALTH	FOIPP	HEALTH INFORMATION	OTHER PRIVACY	HEALTH ADMINISTRATION	STATISTICS/ VITAL STATISTICS
Yukon	none	*Public Health and Safety Act, R.S.Y. 1986, c. 136*	*Access to Information and Protection of Privacy Act, S.Y. 1995, c. 1*	none	none	*Hospital Insurance Services Act, R.S.Y. 1986, c. 85, s. 6* *Health Care Insurance Plan Act, R.S.Y. 1986, c. 81, ss. 5, 19.* *Health Act, S.Y. 1989-90, c. 36, ss. 4, 43*	*Vital Statistics Act, R.S.Y. 1986, c. 175, s. 18, 34, 36, 38-40*
British Columbia	*British Columbia Cancer Agency Research Information Regulation, B.C. Reg. 286/91*	*Health Act, R.S.B.C. 1996, c. 179, ss. 9-10*	*Freedom of Information and Protection of Privacy Act, R.S.B.C. 1996, c. 165*	none	*Privacy Act, R.S.B.C. 1996, c. 373*	*Medicare Protection Act, R.S.B.C. 1996, c. 286, s. 49*	*Statistics Act, R.S.B.C. 1996, c. 439, ss. 4, 5, 7, 9, 11, 12* *Vital Statistics Act, R.S.B.C. 1996, c. 479, ss. 17, 18, 43, 45, 46*
Alberta	*Cancer Programs Act, R.S.A. 1980, c. C-1, Part 1.1* *Cancer Programs Regulation, AR 242/98*	*Public Health Act, S.A. 1984, c. P-27.1*	*Freedom of Information and Protection of Privacy Act, S.A. 1994, c. F-18.5, s. 22.03*	*Health Information Act, Bill 40, 2nd Sess., 24th Leg., Alberta, 1999*	none	*Alberta Health Care Insurance Act, R.S.A. 1980, c. A-24, s. 13* *Alberta Health Care Insurance Regulation, AR 216/81, s. 23* *Hospitals Act, R.S.A. 1980, c. H-11, s. 40*	*Statistics Bureau Act, R.S.A. 1980, c. S-22, ss. 2, 3, 6, 8-10* *Vital Statistics Act, R.S.A. 1980, c. V-4, ss. 14, 15, 38-40*

	CANCER	PUBLIC HEALTH	FOIPP	HEALTH INFORMATION	OTHER PRIVACY	HEALTH ADMINISTRATION	STATISTICS/ VITAL STATISTICS
Saskatchewan	*Cancer Foundation Act, S.S. 1979, c. C-2.1, ss. 2, 11, 12, 15-17*	*Public Health Act. 1994, S.S. 1994, c. P-37.1, s. 31*	*Freedom of Information and Protection of Privacy Act, S.S. 1990-91, c. F-22.01 Local Authority Freedom of Information and Protection of Privacy Act, S.S. 1990-91, c. L-27.1 Local Authority Freedom of Information and Protection of Privacy Amendment Regulations, 1994, Sask. Reg. 51/94, s. 2*	*Health Information Protection Act, S.S. 1999, c. H-0.021 [not yet in force]*	*Privacy Act, R.S.S. 1978, c. P-24*	*Department of Health Act, R.S.S. 1978, c. D-17, ss. 6, 11 Saskatchewan Medical Care Insurance Act, R.S.S. 1978, c. S-29, s. 37*	*Statistics Act, R.S.S. 1978, c. S-58, ss. 4, 6, 7, 9, 11-17 Vital Statistics Act, 1995, S.S. 1995, c. V-7.1, ss. 18, 49, 51, 52, 57*
Manitoba	*Cancer Treatment and Research Foundation Act, R.S.M. 1987, c. C20, ss. 7, 9*	*Public Health Act, R.S.M. 1987, c. P210, ss. 2, 28, 33 Diseases and Dead Bodies Regulation, Man. Reg. 338/88, ss. 2, 6, 9, 10, 19, Schedule B*	*Freedom of Information and Protection of Privacy Act, S.M. 1997, c. 50; C.C.S.M., c. F175*	*Personal Health Information Act, S.M. 1997, c. 51; C.C.S.M., c. P33.5 Personal Health Information Regulation, Man. Reg. 245/97*	*Privacy Act, R.S.M. 1987, c. P125*	*Department of Health Act, R.S.M. 1987, c. H20, s. 5 [Health Services Insurance Act, R.S.M. 1987, c. H35]*	*Statistics Act, R.S.M. 1987, c. S205, ss. 3, 6, 8, 9, 11-13 Vital Statistics Act, R.S.M. 1987, c. V60, ss. 14, 31, 40, 41, 49.1*

	CANCER	PUBLIC HEALTH	FOIPP	HEALTH INFORMATION	OTHER PRIVACY	HEALTH ADMINISTRATION	STATISTICS/ VITAL STATISTICS
Ontario	*Cancer Act, R.S.O. 1990, c. C.1, ss. 5-7*	*Health Protection and Promotion Act, R.S.O. 1990, c. H.7, s. 5*	*Freedom of Information and Protection of Privacy Act, R.S.O. 1990, c. F.31*	*Personal Health Information Protection Act, 1997 [draft – not in force]*	*none*	*Health Cards and Numbers Control Act, 1991, S.O. 1991, c. 1, s. 2* *General Regulation, O. Reg. 147/91 (under Health Cards and Numbers Control Act, 1991), s. 1* *Ministry of Health Act, R.S.O. 1990, c. M.26, s. 6* *Hospital Management Regulation, R.R.O. 1990, Reg. 965 (under Public Hospitals Act), ss. 22-23* *General Regulation, O. Reg. 57/92 (under the Independent Health Facilities Act), s. 12*	*Statistics Act, R.S.O. 1990, c. S.18, ss. 2, 4, 6, 8* *Vital Statistics Act, R.S.O. 1990, c. V.4, ss. 2, 3, 7.1, 21, 43, 53, 57*
Quebec	*none*	*Public Health Protection Act, R.S.Q., c. P-35, ss. 1, 2, 4, 5, 31, 71*	*An Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information, R.S.Q., c. A-2.1, s. 125*	*none*	*Charter of Human Rights and Freedoms, R.S.Q., c. C-12, ss. 4, 5, 9.* *An Act Respecting the Protection of Personal Information in the Private Sector, R.S.Q., c. P-39.1* *Civil Code of Quebec, articles 23, 24, 35*	*Health Insurance Act, R.S.Q., c. A-29, ss. 9.0.0.1., 63, 65, 67* *Hospital Insurance Act, R.S.Q., c. A-28, ss. 12, 15* *An Act Respecting the Ministère De La Santé et Des Services Sociaux, R.S.Q., c. M-19.2, ss. 1, 3* *An Act Respecting Health Services and Social Services, R.S.Q., c. S-4.2, ss. 19, 19.1, 19.2, 346, 373* *(as amended by An Act to amend the Act respecting health services and social services as regards access to users' records, S.Q. 1999, c. 45)* *Professions Code, R.S.Q. c. C-26* *Medical Act, R.S.Q., c. M-9, s. 42*	*Public Health Protection Act, R.S.Q., c. P-35, s. 47* *Act respecting the Bureau de la statistique, R.S.Q., c. B-8 (repealed)*

	CANCER	PUBLIC HEALTH	FOIPP	HEALTH INFORMATION	OTHER PRIVACY	HEALTH ADMINISTRATION	STATISTICS/ VITAL STATISTICS
New Brunswick	none	Public Health Act, S.N.B. 1998, c. P-22.4, ss. 3, 27, 30, 52, 57, 65, 66	Protection of Personal Information Act, S.N.B. 1998, c. P-19.1 [not yet in force] Right to Information Act, S.N.B. 1978, c. R-10.3	none	none	General Regulation, N.B. Reg. 92-84 (under the Hospital Act), s. 21 Medical Services Payment Act, R.S.N.B. 1973, c. M-7, ss. 1, 8	Statistics Act, S.N.B. 1984, c. S-12.3, ss. 3, 4, 7, 8, 12-14, 16 Vital Statistics Act, S.N.B. 1979, c. V-3, ss. 29, 29, 43, 45, 50, 52
Prince Edward Island	none	Public Health Act, R.S.P.E.I. 1988, c. P-30, ss. 1(f), 3, 22 Notifiable and Communicable Diseases Regulations, P.E.I. Reg. EC 330/85, ss. 1(f), 17				Hospital and Diagnostic Services Insurance Act, R.S.P.E.I. 1988, c. H-8, ss. 2, 6 Health Services Payment Act, R.S.P.E.I. 1988, c. H-2, ss. 2, 17 Hospital Management Regulation, P.E.I. Reg. EC 574/76, s. 47 (under the Hospitals Act) Provincial Health Number Act, S.P.E.I. 1997, c. 37, s. 2	Vital Statistics Act, S.P.E.I. 1996, c. 48, ss. 1(k), 19, 20, 22, 37 Vital Statistics Regulations, P.E.I. Reg. EC 703/60, s. 38
Nova Scotia	Queen Elizabeth II Health Sciences Centre Act, S.N.S. 1995-96, c. 15, ss. 4, 25(2) [Cancer Treatment and Research Foundation Act, R.S.N.S. 1989, c. 55 - repealed]	Health Act, R.S.N.S. 1989, c. 195, s. 101	Freedom of Information and Protection of Privacy Act, S.N.S. 1993, c. 5 Freedom of Information and Protection of Privacy Regulations, N.S. Reg. 105/94, s. 9			Hospitals Act, R.S.N.S. 1989, c. 208, s. 71 Health Services and Insurance Act, R.S.N.S. 1989, c. 197, s. 13	Statistics Act, R.S.N.S. 1989, c. 441 Vital Statistics Act, R.S.N.S. 1989, c. 494, s. 17

	CANCER	PUBLIC HEALTH	FOIPP	HEALTH INFORMATION	OTHER PRIVACY	HEALTH ADMINISTRATION	STATISTICS/ VITAL STATISTICS
Newfoundland	*Cancer Treatment and Research Foundation Act, R.S.N. 1990, c. C-4, ss. 2-4*	*Public Health Act, S.N. 1995, c. P-37.1, s. 3*	*Freedom of Information Act, R.S.N. 1990, c. F-25, s. 10, Schedule*	*none*	*Privacy Act, R.S.N. 1990, c. P-22*	*Medical Care Insurance Act, R.S.N. 1990, c. M-5, s. 12* *Department of Health Act, R.S.N. 1990, c. D-15, s. 6* *Hospitals Act, R.S.N. 1990, c. H-9, s. 35* *Medical Care Insurance Release of Information Order, N.R. 132/97*	*Statistics Agency Act, R.S.N. 1990, c. S-24* *Vital Statistics Act, R.S.N. 1990, c. V-6, ss. 2, 13* *Registration and Release of Information Regulations, C.N.R. 973/96 (under Vital Statistics Act)*
Northwest Territories and Nunavut *(all legislation in force in both Territories except as otherwise noted)*	*Disease Registries Act, R.S.N.W.T. 1988, c.7 (Supp.)* *Reportable Diseases Order, R.R.N.W.T. 1990, c. D-3*	*Public Health Act, R.S.N.W.T. 1988, c.P-12*	*Access to Information and Protection of Privacy Act, S.N.W.T. 1994, c.20* *Access to Information and Protection of Privacy Regulations, R-206-96, s. 8*	*none*	*none*	*Medical Care Act, R.S.N.W.T. 1988, c. M-8, s. 15* *Hospital Standards Regulations, R.R.N.W.T. 1990, c. T-6, ss. 73-74 (N.W.T. only)* *Hospital Insurance and Health and Social Services Administration Act, R.S.N.W.T. 1988, c. T-3, s. 5* *Scientists Act, R.S.N.W.T. 1988, c. S-4*	*Vital Statistics Act, R.S.N.W.T. 1988, c.V-3, ss. 19, 44-46, 57* *Access to Records Regulations, R.R.N.W.T. 1990, c.V-1 (under the Vital Statistics Act)*
Federal	*none*	*none*	*Privacy Act, R.S.C. 1985, c. P-21* *Access to Information Act, R.S.C. 1985, c. A-1*	*none*	*Bill C-6, Personal Information Protection and Electronic Documents Act, 2nd Sess., 36th Parl., 1999, Part 1*	*Department of Health Act, S.C. 1996, c. 8; R.S.C. 1985, c. H-3.2, s. 4*	*Statistics Act, R.S.C. 1985, c. S-19, s. 22*

Cancer Legislation Provisions According to Subject

1. Sources of data

(A) REPORTING REQUIREMENTS

Yukon

BRITISH COLUMBIA

Health Act

9 (1) The British Columbia Cancer Agency may request a person to supply it with information or records or classes of information or records that may be prescribed by the minister for the purposes of this section.

9 (3) Subject to any other enactment, a person to whom a request is made under subsection (1) must comply with the request in the manner and at the times requested if the information or records are within the person's possession or control.

104 (1) It is an offence to contravene this Act or a regulation, bylaw, order, direction or permit made under this Act and every day the contravention continues constitutes a separate offence.

(2) The penalty for an offence under subsection (1) for which this Act does not provide a penalty is a fine not exceeding $2 000 or imprisonment for a term not exceeding 6 months, or both.

British Columbia Cancer Agency Research Information Regulation

Information that may be requested by the agency pursuant to section 5.1 (1) of the Act is limited to information listed in Appendices 1 to 3.

Appendix 1: Personal Identification Information

1. Personal identifiers
   (a) name;
   (b) sex;
   (c) birthdate and place;
   (d) marital status;
   (e) residence information.
2. Family identifiers
   (a) spouse's name.
3. Health identifiers
   (a) health insurance number;
   (b) personal health number.

Appendix 2: Medical Information

1. Records from medical laboratories, imaging services, hospitals and other health facilities and physicians.
2. Mortality and morbidity data including autopsy reports.

Appendix 3: Factors Which Influence the Occurrence of Cancer in Human Populations

1. Instrinic host factors;
   (a) ethnicity;
   (b) medical history.

ALBERTA

Cancer Programs Act

20.1 In this Part, ***"reportable cancer"*** means a cancer specified by the regulations as a reportable cancer.

20.5(1) A physician who knows or has reason to believe that a patient under the physician's care or supervision has a reportable cancer shall, as soon as practicable, provide the board with the information prescribed by the regulations.

(2) A person who is responsible for a laboratory in which an examination of a specimen from a human body is conducted that reveals a reportable cancer shall, as soon as practicable, provide the board with the information prescribed by the regulations.

Cancer Programs Regulation, **AR 242/98**

1. In this Regulation, ***"reportable cancer"*** means a cancer on the list adopted under subsection (2).
2. The list of all diseases classified as malignant, in situ or metastatic in the International Classification of Diseases for Oncology, as amended from time to time, published by the World Health Organization, is adopted as the list of reportable cancers.
3. The following information must be provided to the board under section 20.5(1) of the Act by a physician who knows or has reason to believe that a patient under the physician's care or supervision has a reportable cancer:
   (a) the following patient data:
      (i) name, including last name, maiden name if applicable and first name, and initials for any other names;
      (ii) sex;
      (iii) date of birth;
      (iv) place of birth;
      (v) Alberta personal health number;
      (vi) patient's address (including postal code) at time of diagnosis;
      (vii) vital status;
      (viii) diagnosis;
      (ix) date of diagnosis;
      (x) method of diagnosis;
      (xi) name and address of physician;
      (xii) treatment (type and date) administered to the patient;
   (b) the following tumour data:
      (i) anatomical localization of the tumour;
      (ii) morphology of the tumour;
      (iii) histologic grade of tumour;
      (iv) stage of the disease at diagnosis;
      (v) site of metastasis, if appropriate;
      (vi) laterality of tumour, if appropriate;
      (vii) multi-focal tumour, if appropriate;
      (viii) other critical prognostic variables, if appropriate;
      (ix) all clinical and epidemiological information pertinent to the diagnosis and treatment.
4. The following information must be provided to the board under section 20.5(2) of the Act by the person responsible for the laboratory where an examination of a specimen from a human body is conducted that reveals a reportable cancer:
   (a) the following laboratory data:
      (i) name of the laboratory;
      (ii) address of the laboratory;
   (b) the following patient data:
      (i) name, including last name, maiden name if applicable and first name, and initials for any other names;
      (ii) address, if available;
      (iii) Alberta personal health number;
      (iv) date of test result (final report);
   (c) the following site-specific tumour data:
      (i) anatomical localization of the tumour;
      (ii) morphology of the tumour;
      (iii) histologic grade of tumour, if appropriate;
      (iv) information relevant to staging, if appropriate;
      (v) site of metastasis, if appropriate;
      (vi) laterality of tumour, if appropriate;
      (vii) other critical prognostic variables, if appropriate;
      (viii) other information that the laboratory considers appropriate.

SASKATCHEWAN

Cancer Foundation Act

In this Act ***"cancer"*** includes all forms and types of malignant and premalignant conditions;

(i) ***"patient"*** means a person afflicted with cancer;

16(1) Any physician or dentist who examines, diagnoses or treats a patient, or the administrative head of any hospital in which a patient is examined, diagnosed or treated, shall furnish to an official of the foundation any information with respect to that examination, diagnosis or treatment that the official may request.

MANITOBA

Diseases and Dead Bodies Regulation

1. In this Part ***"reportable disease"*** means cancer or malignant neoplasm or a communicable disease listed in Schedule A
2. Without delay after becoming aware that a person is suffering from cancer or malignant neoplasm, a health professional shall report the disease on Form 3 of Schedule B.
3. 9(1) Every duly qualified medical practitioner treating a patient who dies from a reportable disease shall forthwith report the death to the medical officer of health and the director on Form 5 of Schedule B.

   9(2) Where a person suffering froma reportable disease dies in any hospital, the superintendnat or other person in charge of the hospital shall forthwith report the death to the medical officer of health and the director on Form 5 of Schedule B.
4. Every person who, in performing a biopsy or autopsy, discovers evidence of a reportable disease, shall report the nature of that evidence to the director, together with the name and address of the person on whom the autopsy was made, or from whom the tissue was taken, and the name and address of the duly qualified medical practitioner, if any, who is, or had been, attending the person on whom the autopsy was made or from whom the tissue was taken.
5. 19(1) Every medical officer of health shall keep an accurate record in writing of
   (a) every case of a reportable disease reported to him or her by a duly qualified medical practitioner; and
   (b) every other case of a reportable disease
   (i) otherwise reported to him or her, or
   (ii) of which he or she has knowledge.

   19(2) A medical officer of health shall send to the director by mail, within 24 hours after receipt thereof,
   (a) every report of a case of a reportable disease received by him or her froma duly qualified medical practitioner; and
   (b) full information regarding any other case of a reportable disease of which he or she may be aware.

Schedule B
Form 3: Report of Malignant Neoplasm
Form 5: Notification of Death from Reportable Disease

Public Health Act

33(1) A person who contravenes or fails to comply with any provision of this Act or the regulations, or who disobeys or fails to comply with or carry out an order or direction lawfully made or given under this Act or the regulations, is guilty of an offence and liable, on summary conviction, to a fine not exceeding $5,000. or to imprisonment for a term not exceeding three months, or to both.

ONTARIO

QUEBEC

NEW BRUNSWICK

PRINCE EDWARD ISLAND

Public Health Act

1. (f) ***"notifiable disease"*** and ***"notifiable condition of ill health"*** mean those diseases, injuries or other conditions of ill health designated by regulation, any incidence of which must be reported to the Chief Health Officer
2. Any person who fails to comply with or otherwise contravenes any provision of this Act or any regulation or order made thereunder ... is guilty of an offence and is liable on summary conviction to a fine not exceeding $1,000 or to imprisonment for a term not exceeding six months or both.

Notifiable and Communicable Diseases Regulations

In these regulations the following are notifiable diseases and conditions, the occurrence of which must be reported to the Chief Health Officer or his delegate in such manner as the Chief Health Officer may direct:

Malignant Neoplasm

NOVA SCOTIA

Health Act

101 (1) Every medical practitioner who attends or treats a person who has cancer or who makes a diagnosis of cancer, the superintendent of every hospital or institution in which patients are being diagnosed or treated and any other person or agency required by the Minister in writing shall, within ten days after a diagnosis of cancer in any form has been

established, report the case on a form prescribed by the Minister to the Executive Director of the Cancer Treatment and Research Foundation of Nova Scotia or such other person as may be designated by the Minister.

127 Each day that a person commits an offence under this Act or the regulations constitutes a separate offence.

128 Each person who contravenes or fails to comply with any provision of this Act or the regulations for which no other penalty is prescribed is guilty of an offence and is liable on summary conviction to a fine of not less than one hundred dollars and not more than five hundred dollars.

NEWFOUNDLAND

NORTHWEST TERRITORIES AND NUNAVUT

Reportable Diseases Order

1. In this order, "ICD" means the International Classification of Diseases, ninth revision. *(CIM)*
2. Pursuant to paragraph 2(a) of the *Disease Registries Act*, the following are declared to be reportable diseases:
   (a) Malignant Neoplasms (ICD nos. 140-208);
   (b) Carcinoma in situ (ICD nos. 230-234);
   (c) Neoplasms of uncertain behavior or unspecified nature (ICD nos. 235-239).

Disease Registries Act

1. A health care professional who examines, diagnoses or treats a person in respect of a reportable disease shall provide the Registrar, on a form approved by the Registrar, with
   (a) the name, address and profession of the health care professional who performed the examination, diagnosis or treatment;
   (b) the name, address, sex and age of the person who has the reportable disease;
   (c) a description of the condition of the person who has the reportable disease and the nature and state of the reportable disease in respect of that person; and
   (d) any other information that the Registrar considers necessary with respect to
      (i) the examination, diagnosis or treatment, and
      (ii) the person who has the reportable disease.

2. A health care professional who performs or causes to be performed a reportable test on a person shall provide the Registrar, on a form approved by the Registrar, with
   1. the name, address and profession of the health care professional who performed or caused to be performed the reportable test;
   (b) the name, address, sex and age of the person on whom the test was performed; and
   (c) any other information that the Registrar considers necessary with respect to
      1. the performance of the test, and
      (ii) the person on whom the test was performed.

3. Where an examination, diagnosis or treatment of a person in respect of a reportable disease or a reportable test takes place in a health facility, the person in charge of the health facility shall, on the request of the Registrar, provide to the Registrar any additional information that the Registrar considers necessary respecting
   (a)the examination, diagnosis, treatment or test; and
   (b) the person who has the disease or on whom the test was performed.

4. Every person who contravenes this Act is guilty of an offence and liable on summary conviction to a fine not exceeding $500 or to imprisonment for a term not exceeding 30 days or to both.

(B) COLLECTION OF DATA FROM OTHER SOURCES

YUKON

BRITISH COLUMBIA

Health Act

9 (1) The British Columbia Cancer Agency may request a person to supply it with information or records or classes of information or records that may be prescribed by the minister for the purposes of this section.

British Columbia Cancer Agency Research Information Regulation

Information that may be requested by the agency pursuant to section 5.1 (1) of the Act is limited to information listed in Appendices 1 to 3.

Appendix 1: Personal Identification Information

1. Personal identifiers
    - (a) name;
    - (b) sex;
    - (c) birthdate and place;
    - (d) marital status;
    - (e) residence information.
2. Family identifiers
    - (a) spouse's name.
3. Health identifiers
    - (a) health insurance number;
    - (b) personal health number.

Appendix 2: Medical Information

1. Records from medical laboratories, imaging services, hospitals and other health facilities and physicians.
2. Mortality and morbidity data including autopsy reports.

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1. Instrinic host factors;
    - (a) ethnicity;
    - (b) medical history.

ALBERTA

Cancer Programs Act

20.2 (3) The cancer registry may, subject to any directions specified in the regulations, contain information
- (a) obtained under section 13(3) of the Alberta Health Care Insurance Act,
- (b) obtained under the Hospitals Act from a hospital that is not a provincial cancer hospital,
- (c) obtained from the board's hospitals, out-patient clinics and programs, and
- (d) obtained from any other source specified by the Minister.

20.5 (3) After receiving information under subsection (1) or (2), the board may request the physician or person responsible for the laboratory to provide any additional information that the board considers necessary respecting the reportable cancer, the person who has cancer or the examination.

SASKATCHEWAN

Cancer Foundation Act

In this Act ***"cancer"*** includes all forms and types of malignant and premalignant conditions;

(i) ***"patient"*** means a person afflicted with cancer;

16(1) Any physician or dentist who examines, diagnoses or treats a patient, or the administrative head of any hospital in which a patient is examined, diagnosed or treated, shall furnish to an official of the foundation any information with respect to that examination, diagnosis or treatment that the official may request.

MANITOBA

ONTARIO

QUEBEC

NEW BRUNSWICK

PRINCE EDWARD ISLAND

NOVA SCOTIA

NEWFOUNDLAND

NORTHWEST TERRITORIES AND NUNAVUT

Disease Registries Act

1. 6. (1) After receiving information from a health care professional under section 3 or 5, the Registrar may request the professional to provide any additional information that the Registrar considers necessary respecting
(a)the examination, diagnosis or treatment; and
(b) the person who has the disease.

2. The health care professional shall comply with a request of the Registrar made under subsection (1).

2. Management

(A) ADMINISTRATION

YUKON

BRITISH COLUMBIA

ALBERTA

***Cancer Programs Act*, R.S.A. 1980, c. C-1**

20.2(1) The board shall, subject to the regulations, establish a cancer registry.
(2) The cancer registry must contain the information respecting reportable cancers obtained under section 20.5.

20.9 The Minister may make regulations
(c) respecting the establishment and operation of the cancer registry, including regulations requiring the board to enter certain information in the cancer registry;

***Cancer Programs Regulation*, AR 242/98**

2(1) There is hereby established the Cancer Registry.
(2) The board must register the information referred to in sections 3 and 4 in the Cancer Registry.

SASKATCHEWAN

Cancer Foundation Act

1. The foundation shall conduct a program for the diagnosis, prevention and treatment of cancer which shall include:
(e) the adequate reporting of cases of cancer and the recording and compilation of data relating to cancer;

2. For the purposes of carrying out the provisions of this Act, the foundation may:
(a) enter into agreements with the Government of Saskatchewan, The University of Saskatchewan, The University of Regina, any hospital or any physician or other person;
(e) do any other things that it considers necessary or advisable.

3. 15(1) The foundation shall maintain a register of patients containing the names of all persons registered as patients by the Saskatchewan Cancer Commission under The Cancer Control Act and, in accordance with the regulations, any other persons who become patients.

MANITOBA

Cancer Treatment and Research Foundation Act

1. The objects of the foundation are the conduct of a program of diagnosis of, treatment of, and research in, cancer including
(d) the adequate reporting of cases of cancer and the recording and compilation of data relating to cancer;

2. The foundation may, with the approval of the Lieutenant Governor in Council, enter into an agreement with a university, medical association, hospital, or other association, corporation, or person, for the purpose of carrying out the objects of the foundation.

ONTARIO

Cancer Act

1. The object of the Foundation is to establish and conduct a program of research, diagnosis and treatment in cancer, including,
   (f) the adequate reporting of cases and the recording and compilation of data;
2. The Foundation may make agreements with universities, medical associations, hospitals and persons for the purpose of carrying out the object of the Foundation.

QUEBEC

NEW BRUNSWICK

PRINCE EDWARD ISLAND

NOVA SCOTIA

NEWFOUNDLAND

Cancer Treatment and Research Foundation Act

The objects of the foundation are the establishment and conduct of a program of diagnosis of, treatment of and reserach in, cancer, including,

(e) the adequate reporting of cases of cancer and the recording and compilation of data relating to cancer

NORTHWEST TERRITORIES AND NUNAVUT

Disease Registries Act

1. The Registrar shall establish and maintain a register for each reportable disease and each reportable test.
2. The Registrar is responsible
   (a) for the form of the registers; and
   (b) for ensuring that the registers contain the information provided to the Registrar by health care professionals under this Act.
3. The Minister may appoint a Registrar of Disease Registries.

(B) SECURITY

YUKON

BRITISH COLUMBIA

ALBERTA

SASKATCHEWAN

MANITOBA

ONTARIO

QUEBEC

NEW BRUNSWICK

PRINCE EDWARD ISLAND

NOVA SCOTIA

NEWFOUNDLAND

NORTHWEST TERRITORIES AND NUNAVUT

(C) DATA QUALITY

YUKON

BRITISH COLUMBIA

ALBERTA

Cancer Programs Regulation

1. In this Regulation, ***"reportable cancer"*** means a cancer on the list adopted under subsection (2).
2. The list of all diseases classified as malignant, in situ or metastatic in the International Classification of Diseases for Oncology, as amended from time to time, published by the World Health Organization, is adopted as the list of reportable cancers.

SASKATCHEWAN

Cancer Foundation Act

In this Act ***"cancer"*** includes all forms and types of malignant and premalignant conditions;

MANITOBA

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NORTHWEST TERRITORIES AND NUNAVUT

Reportable Diseases Order

1. In this order, "ICD" means the International Classification of Diseases, ninth revision.
2. Pursuant to paragraph 2(a) of the *Disease Registries Act*, the following are declared to be reportable diseases:
   (a) Malignant Neoplasms (ICD nos. 140-208);
   (b) Carcinoma in situ (ICD nos. 230-234);
   (c) Neoplasms of uncertain behavior or unspecified nature (ICD nos. 235-239).

3. Confidentiality, access and use of data

YUKON

BRITISH COLUMBIA

Health Act

9 (7) A person who has obtained information or records pursuant to a request made under subsection (1) must not disclose the information or records to another person except

(a) for the purpose of medical research and to a person engaged in medical research whether or not the person is engaged in medical research for the British Columbia Cancer Agency,

(b) in court proceedings related to this Act or a regulation,

(c) under an agreement that

(i) is between the British Columbia Cancer Agency and a government, government agency or another organization engaged in medical research,

(ii) relates to medical research, and

(ii provides for the disclosure of information and records to that government, government agency or other organization, or

(d) for the purpose of compiling statistical information by an organization, a government or a government agency if the information is compiled to facilitate medical research.

ALBERTA

Cancer Programs Act

20.3(1) The information in the cancer registry is private and confidential.

Section 40 of the Hospitals Act does not apply to information in the cancer registry.

20.4 The information in the cancer registry is to be used for the following purposes:

(a) to assess and improve the standards of treatment and care provided to cancer patients;

(b) to assist in the treatment and care of the person who is the subject of the information;

(c) to assist in cancer research, education and prevention;

(d) to compile statistics on cancer;

(e) any other purpose specified by the Minister.

20.6 (1) The Minister or the board with the approval of the Minister may enter into an agreement with the Government of Canada or the government of a province or with any person that relates to the disclosure of information in the cancer registry.

(2) An agreement under subsection (1) shall require that the information disclosed remain confidential.

20.7 (1) The board may use the information in the cancer registry for the purposes referred to in section 20.4.

(2) The board shall disclose the information in the cancer registry

(a) to the Minister in the manner and form specified by the Minister,

(b) to any person specified by the Minister where the Minister believes it is in the public interest that the information be disclosed to that person, and

(c) to any person when required by law.

(3) The board may disclose the information in the cancer

(a) to the person who is the subject of the information or to that person's designate or legal representative;

(b) in statistical form if the person who is the subject of the information is not revealed or made identifiable;

(c) to a person conducting bona fide research or a medical review if the disclosure is made in a manner that ensures the confidentiality of the information;

(d) to a person authorized to receive the information under an agreement referred to in section 20.6;

(e) to a person or class of persons authorized to receive the information by the regulations.

20.8 (1) No person shall disclose information in the cancer registry to a person unless disclosure of information to that person is authorized under section 20.7.

(2) No person shall review or examine the information in the cancer registry unless disclosure of the information to that person is authorized under section 20.7.

(3) A person who contravenes subsection (1) or (2) is guilty of an offence and is liable to a fine of not more than $10 000.

20.9 The Minister may make regulations

(d) authorizing the board to disclose information in the cancer registry to a person or class of persons.

SASKATCHEWAN

MANITOBA

ONTARIO

Cancer Act

7.(1) Any information or report respecting a case of cancer furnished to the Foundation by any person shall be kept confidential and shall not be used or disclosed by the Foundation to any person for any purpose other than for compiling statistics or carrying out medical or epidemiological research.

QUEBEC

NEW BRUNSWICK

PRINCE EDWARD ISLAND

Public Health Act

22 (1) Each person employed in the administration of this Act shall preserve secrecy with respect to all matters that come to his knowledge in the course of his employment and which pertain to health services rendered in that regard, and shall not communicate any matters to any other person except as provided in this section.

(2) Nothing in this section prevents the divulging of information

(a) with the consent of the person to whom the information relates, or

(b) to the extent that the Chief Health Officer directs in the best interest of that person or the public.

(3) Nothing in this section prevents the publication of reports or statistical compilations relating to health which do not identify individual cases or personalized sources of information.

Any person who fails to comply with or otherwise contravenes any provision of this Act or any regulation or order made thereunder ... is guilty of an offence and is liable on summary conviction to a fine not exceeding $1,000 or to imprisonment for a term not exceeding six months or both.

NOVA SCOTIA

Health Act

101 (2) Every report made under this Part is confidential and no person engaged in the administration of this Part shall disclose any such report or any part of its contents to any person except in the performance of his duties.

127 Each day that a person commits an offence under this Act or the regulations constitutes a separate offence.

128 Each person who contravenes or fails to comply with any provision of this Act or the regulations for which no ther penalty is prescribed is guilty of an offence and is liable on summary conviction to a fine of not less than one undred dollars and not more than five hundred dollars.

NEWFOUNDLAND

NORTHWEST TERRITORIES AND NUNAVUT

Disease Registries Act

1. 10.1 Where there is a conflict or inconsistency between sections 11 to 20 of this Act and any provision of the *Access to Information and Protection of Privacy Act*, those sections of this Act shall prevail to the extent of the conflict or inconsistency.

12. Subject to sections 14 to 18, the Registrar shall ensure that information provided to the Registrar under this Act is kept confidential and is not disclosed to any person, including employees or agents of the Government of the Northwest Territories.

13. No person shall review or examine a register or information provided to the Registrar under this Act unless the person is authorized to have access to the register or information by sections 14 to 18.

14. (1) The Minister, Registrar, Deputy Minister of the department responsible for the administration of this Act, and one or more persons designated by the Minister may review a register.

(2) The persons referred to in subsection (1) may use the information contained in a register

(a)to prepare accurate estimates on the number of people in the Territories who have a reportable disease;

(b) to identify patterns of a reportable disease;

(c)to assist in determining ways to reduce the incidence of a reportable disease in the Territories; and

(d) to assist in the development of programs and policies designed to improve the health of the residents of the Territories.

15. The Registrar may disclose information in a register to a health care professional where, in the opinion of the Registrar, the disclosure is necessary for the treatment of the person who is the subject of the information.

16. (1) The Minister and the Commissioner may, on behalf of the Government of the Northwest Territories, enter into agreements with the Government of Canada relating to the disclosure of information contained in a register.

(2) The Minister may, on behalf of the Government of the Northwest Territories, enter into agreements with the government of a province or the Yukon Territory relating to the disclosure of information contained in a register.

(3) The Registrar may disclose information in accordance with an agreement referred to in subsection (1) or (2).

17. (1) A person who is from a jurisdiction that has not entered into an agreement with the Government of the Northwest Territories under section 16 and has functions similar to those of the Registrar may apply to the Registrar to be provided with information contained in a register.

(2) The Registrar may release information in the form of general statistics to a person who applies under subsection(1).

18. (1) A person, other than a person referred to in subsection 17(1), who wishes access to the information contained in a register for the purposes of medical, epidemiological or other research may apply to the Registrar, on a form approved by the Registrar, for that access.

(2) In an application, an applicant shall
(a)state his or her qualifications to conduct the research;
(b)state the purpose for which the information is to be used; and
(c)provide any other information that the Registrar considers necessary.

(3) The Registrar may provide an applicant with access to a register if
(a)the Registrar is satisfied that the applicant is qualified to do the research and that the research may benefit the residents of the Territories; and
(b)the applicant pays the fee determined by the regulations.

19. A person who is provided access to a register under subsection 18(3) shall not
(a) use or communicate any information obtained from the register for any purpose except the purpose stated in his or her application; or
(b) disclose the name or any means of identifying

(i) a person who is the subject of the information provided to the Registrar under this Act, unless that person consents in writing to the disclosure,

(ii) a health care facility in which a person having a reportable disease was examined, diagnosed or treated or in which a reportable test was performed, unless the person in charge of the health facility consents in writing to the disclosure, or

(iii) a health care professional who provided information to the Registrar under this Act, unless the health care professional consents in writing to the disclosure.

20. (1) A person who is provided access to a register under subsection 18(3) and who intends to publish material based on information obtained under section 18 shall provide the Registrar with a copy of the material before publication.

(2) Where, in the opinion of the Registrar it is in the public interest to do so, the Registrar may require the person referred to in subsection (1) to include a disclaimer provided by the Registrar in any publication of material referred to in subsection (1).

21. A person who is provided access to a register under subsection 18(3) and who publishes material based on information obtained under section 18 shall
(a) ensure that the published material
(i) acknowledges that the source of the material is information provided by the Registrar under the authority of this Act, and
(ii) contains the disclaimer referred to in subsection 20(2), if required; and
(b) provide the Registrar with a copy of the published material.

23. Every person who contravenes this Act is guilty of an offence and liable on summary conviction to a fine not exceeding $500 or to imprisonment for a term not exceeding 30 days or to both.

4. Liability

YUKON

BRITISH COLUMBIA

Health Act

9 (8) An action for damages does not lie for anything done or omitted in good faith in the exercise or purported exercise of the powers conferred or an obligation imposed by this section.

ALBERTA

Cancer Programs Act

20.5(4) No action or other proceeding for damages lies against a physician or person responsible for a laboratory for providing information to the board under this section.

SASKATCHEWAN

Cancer Foundation Act

16(2) No action or other proceeding for damages lies against any physician, dentist or hospital in respect of the furnishing to the foundation of any information or report with respect to any case of cancer examined, diagnosed or treated, by that physician or dentist, or at that hospital.

MANITOBA

ONTARIO

Cancer Act

7.(2) No action or other proceeding for damages lies or shall be instituted against any legally qualified medical practitioner or any licensed dental surgeon or any hospital in respect of the furnishing to the Foundation of any information or report with respect to a case of cancer examined, diagnosed or treated by such medical practitioner or dental surgeon or at such hospital.

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NOVA SCOTIA

NEWFOUNDLAND

NORTHWEST TERRITORIES AND NUNAVUT

Disease Registries Act

No action or other proceeding for damages lies against a health care professional or person in charge of a health facility in respect of the providing of any information to the Registrar under this Act.

5. Funding

YUKON

BRITISH COLUMBIA

ALBERTA

Cancer Programs Act

The Lieutenant Governor in Council may provide financial assistance to promote and encourage programs and measures for the prevention of cancer or for cancer research.

SASKATCHEWAN

Cancer Foundation Act

1. The foundation may receive donations and any moneys received as a donation shall be invested, subject tot he terms of the donation, in accordance with section 19.
2. The funds of the foundation shall consist of moneys paid to it pursuant to section 32 and received by it from any other source, and the foundation may, in accordance with this Act, disburse, expend or otherwise deal with any of its funds in any manner that it considers advisable.
3. There may be paid annually to the foundation out of the consolidated fund any moneys that may be appropriated by the Legislature for the purposes of this Act.

MANITOBA

Cancer Treatment and Research Foundation Act

The funds of the foundation consist of money received by it from any source including moneys granted to it for its use by the Parliament of Canada or the Legislature of Manitoba and the foundation has charge, control, and management, of its funds and property and may disburse, expend, or otherwise deal with any of its funds or property in such manner consistent with its objects as it may deem proper.

ONTARIO

Cancer Act

The funds of the Foundation consist of money received by it from any source including money appropriated for its use by the Parliament of Canada or the Legislature of Ontario, and the Foundation may disburse, expend or otherwise deal with any of its funds in such manner not contrary to law as it considers proper.

QUEBEC

NEW BRUNSWICK

PRINCE EDWARD ISLAND

NOVA SCOTIA

NEWFOUNDLAND

Cancer Treatment and Research Foundation Act

The funds of the foundation shall consist of money received by it, including money granted to it by the Legislature, and the foundation shall have charge, control and management of its funds and property and may disburse, spend or otherwise deal with its funds or property in the manner consistent with its objects that it considers appropriate.

NORTHWEST TERRITORIES AND NUNAVUT

Disease Registries Act

The Registrar may provide an applicant with access to a register if

(b)the applicant pays the fee determined by the regulations.

APPENDIX C

Recommended Performance Characteristics

A. General (routine) reporting requirements

1. Legislation must give clear authority to the designated agency (i.e. cancer information custodian) to implement, maintain and use a population-wide cancer surveillance system - this includes authority to collect, store and use patient information/records as well as tissue and other biologic specimens.

2. Legislation or regulations should:
   - (a) define reportable conditions and procedures, e.g. reportable cancers include all malignant and in-situ neoplasms (as defined in ICD-9 or ICDO-2). Exceptions would include not reporting basal and squamous cell carcinomas of the skin, but possibly reporting benign and uncertain behaviour neoplasms of the CNS.
   - (b) define a starting reference date for the reporting requirements, i.e. cases diagnosed on or after the reference date must be reported.
   - (c) define residency requirements of patients with reportable conditions and procedures. Ideally, this should include all residents and non-residents of the population – facilitates sharing cases with other registries, etc.
   - (d) define who is responsible for reporting the data:
     - all hospitals and other designated health care facilities providing screening, diagnostic and /or therapeutic services with respect to cancer, including ambulatory surgery centres, radiotherapy centres
     - all pathology, cytology and hematology laboratories providing diagnostic services with respect to cancer
     - the government agency responsible for reporting deaths (e.g. Registered General), nominal information from Health Insurance Database and possibly other population files
   - (e) define the required immediacy of reporting:
     - for hospitals and other facilities, within 1 month following discharge or within 3 months following admission (whichever is less)
     - for labs, within 1 month following diagnosis
     - for Registered General, within 3 months following death
   - (f) make reference to more detailed documents regarding reporting, e.g.:
     - ICD-9 and ICDO-2
     - the data elements and format (electronic or paper) to be reported by each source
     - special data collection issues and coding manuals?
   - (g) define to whom and under what circumstances the designated agency has the authority to release the data

B. Ad hoc access to patient records (for purpose of registration)

1. Legislation or regulations should provide for access to records of health care providers and facilities by authorized persons that would identify reportable conditions or procedures, or clarify ambiguous reports, or identify additional characteristics of the condition (e.g. basis of diagnosis, treatment, extent of spread), or of the patient (e.g. medical/vital status, residence, health number) or of the procedure (e.g. reason for the test, result of the test) – for the purpose of either case ascertainment, correcting false reporting, completing the collection of reportable data elements or other quality assurance activities.
2. Legislation or regulations should provide that if a provider or facility fails to report requested data, authorized personnel may access the data and report it to the designated agency.

C. Penalty for failure to report

1. Legislation or regulations should provide for penalties for failure to report required data or grant access to all relevant records for the purposes described above.
   (a) the penalties may include:
   - a fine for each day that access is refused
   - revocation or suspension of a practitioner's or facility's license

D. Reporting data of acceptable quality

1. Legislation or regulations should provide that data reported to the designated agency meet standards of accuracy and completeness as developed and promulgated by the agency.

E. Confidentiality and disclosure of reported data

1. Legislation must specify the confidential nature of the data in the registry and provide for the confidentiality of all cancer patient data.
2. Legislation or regulations must address how the data are to be released, to whom and for what purpose.
   (a) aggregate data describing cancer incidence, prevalence, treatment, survival, and mortality should be available to the general public through published reports and through data access policies developed and promulgated by the designated agency.
   (b) access to confidential data is restricted, but not so strictly that researchers with approved research projects are denied access.
   - researchers may be granted access to confidential information concerning individual cancer patients, practitioners or facilities provided the following conditions are met:
     (a) the scientific merit and ethics of the proposed research are acceptable to the designated agency,
     (b) the proposed research cannot be reasonably achieved without the disclosure of the requested confidential information, and
     (c) the person(s) to whom the confidential information will be disclosed must agree to comply with conditions relating to security and confidentiality as prescribed by the designated agency.
   (c) The designated agency may exchange patient-specific data with a reporting facility or any other cancer care facility for the purpose of obtaining information necessary to complete a registration, provided that this facility complies with the agency's confidentiality policies.
   (d) The designated agency may exchange patient-specific data with other cancer surveillance agencies if reciprocal data sharing agreements that include confidentiality provisions are implemented.
   (e) Wilful violation of confidentiality provisions should be punishable under the legislation.

F. Liability

1. Legislation must provide for protection for individuals and facilities complying with the law, including provisions specifying that no person or facility will be held liable in any civil action for reporting cancer patient data to the designated agency.
2. Staff authorized to release cancer patient data must also be protected from liability for release of cancer patient data to those agreeing to all requirements relating to security and confidentiality as prescribed by the agency.

G. Specification of funding source(s)

1. Legislation or regulations may specify the funding source(s) for the operation of the surveillance system by the designated agency – this could include the charging of reasonable fees by the agency to the public and researchers for the purpose of filling requests for access to the aggregated or restricted cancer patient data.
   (a) Legislation or regulations may specify where collected fees are to be deposited.

Project Team

Barbara von Tigerstrom - Project Coordinator, Health Law Institute, University of Alberta
Mylène Deschênes - Research Associate, Centre de recherche en droit public, Université de Montréal
Bartha Maria Knoppers - Professor, Centre de recherche en droit public, Université de Montréal
Tim Caulfield - Research Director, Health Law Institute, University of Alberta

Research Assistants

Health Law Institute: Anne Coté, Brian Cohen
Centre de recherche en droit public: Martin Letendre, Dominic Grégoire, Annie Buzzanga

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